
SUPERVISORY GUIDELINE

FOR THE

PATHOGEN REDUCTION/

HACCP REGULATORY REQUIREMENTS

1998

Table of Contents

<u>Page(s)</u>	<u>Topic</u>
1	Purpose
2-4	Background
4-12	Preparing for implementation of all Pathogen Reduction/HACCP regulatory requirements
4-5	HACCP training
5-8	Plant awareness meeting
8	Updating plant profiles
8-12	Establishment/shift procedure plan and work assignment
12-34	Basic compliance/noncompliance
13-21	HACCP basic procedures
13-16	Regulatory requirements for HACCP basic procedures
17-19	Use of the checklist to verify that HACCP plans meet basic regulatory requirements
19-21	Enforcement actions related to HACCP basic procedures
21-26	SSOP basic procedures
21-22	Regulatory requirements for SSOP basic procedures
22-23	Use of checklists to verify that establishment's SSOP meets regulatory requirements
23-26	Enforcement actions related to SSOP basic procedures
26-34	<i>E. coli</i> basic procedures
26-31	Review of regulatory requirements for <i>E. coli</i> basic procedures
31	Use of checklists to verify that <i>E. coli</i> plans meet regulatory requirements
31-34	Enforcement actions related to <i>E. coli</i> basic procedures
35-84	Other Compliance/noncompliance
34-58	HACCP
35-38	HACCP other features
38-48	HACCP other features - inspection procedures
48-55	HACCP other features - determining compliance/noncompliance
55-58	HACCP other features - enforcement actions
58-73	SSOP
58-60	SSOP other requirements
60-64	SSOP other requirements - inspection procedures
64-70	SSOP other requirements - determining compliance/noncompliance
70-73	SSOP other requirements - enforcement actions
73-77	<i>Salmonella</i> sampling
73-74	<i>Salmonella</i> sampling - regulatory requirements
74-76	<i>Salmonella</i> sampling - sampling procedures
76	<i>Salmonella</i> sampling - determining compliance/noncompliance
76-77	<i>Salmonella</i> sampling - enforcement actions
77-83	Consumer protection
78	Consumer protection - regulatory requirements

<u>Page(s)</u>	<u>Topic</u>
78	Consumer protection - inspection procedures
78-82	Consumer protection - determining compliance/noncompliance
82-83	Consumer protection - enforcement actions and phase out of PEA
83-84	Zero tolerance for fecal contamination
85-86	The role of the supervisory in providing technical advice
86-88	Using PBIS data
89	Inspection Procedures 03(B through J)01 - Work Identification Flowchart
90	Inspection Procedures 03(B through J)02 - Work Identification Flowchart
91-93	Index

I. PURPOSE

The purpose of this document is to provide guidance to Field Operations supervisors on how to assign, guide, direct, and assess the work of inspection personnel performing in-plant Basic and Other Compliance/Noncompliance procedures that are designed to support the inspection system activities and enforcement of regulatory requirements in establishments subject to the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) rule. The rule requires that establishments must:

- develop and implement written sanitation standard operating procedures,
- develop and implement HACCP systems,
- meet *Salmonella* performance standards established by FSIS testing, and
- conduct routine testing of carcasses for generic *E. coli* in slaughter operations.

The responsibilities for the enforcement of the regulatory requirements and inspection system activities are discussed in detail in FSIS Directives 5000.1 and 5400.5. This guide will cover considerations for Field Operations supervisors related to preparing to implement the HACCP requirements, determining basic compliance/noncompliance, determining compliance/noncompliance with the other features of an establishment's HACCP system, and instituting appropriate enforcement actions when necessary. The guidance is intended to be used by District Managers, Deputy District Managers, Assistant District Managers for Enforcement, Circuit Supervisors, Multi-IPPS, and Inspector In Charge (IIC) supervisors who are working in the current field environment which integrates domestic and import inspection of meat and poultry products.

II. BACKGROUND

To reduce the occurrence and numbers of pathogenic microorganisms on meat and poultry products, FSIS published the Pathogen Reduction/HACCP rule. These regulations represent a fundamental shift in FSIS's regulatory philosophy from, "command and control," to performance standards, which allow for more industry flexibility. Industry is being required by the regulation to develop plans for controlling food safety hazards that can affect their products. If the plans they design are effective in eliminating health and safety hazards, and if the establishment executes the plan's design properly, then the resulting product should be safe for consumers. Instead of FSIS determining the means by which establishments will meet their responsibility to produce safe, wholesome, and properly labeled products, FSIS will set performance standards that establishments must meet. This means that FSIS will no longer be attempting to, "inspect quality into a product." Inspection's role has become one of regulatory oversight. FSIS will rely less on after-the-fact detection of product and process defects and more on verifying the effectiveness of processes and process controls designed to ensure food safety.

The HACCP system regulations (part 417) apply in all official establishments as of the following dates:

- January 26, 1998, for all establishments with 500 or more employees (designated as "large" establishments);
- January 25, 1999, for all establishments with 10 or more but fewer than 500 employees - unless the establishment has annual sales of less than \$2.5 million (designated as "smaller" establishments); and

- January 25, 2000, for all establishments with fewer than 10 employees or annual sales of less than \$2.5 million (designated as “very small” establishments).

Supervisors have a key leadership role in implementing the changes that are required of the field inspection work force as a result of the rule. This role of leader for change began prior to January 27, 1997, when the sanitation standard operating procedures (SSOP) requirements were implemented. The Pre-HACCP/SSOP Culture Change Supervisory Training Program that was presented in 1996, introduced the Supervisory Blueprint as a tool for leading change. The Supervisory Blueprint illustrates how frontline supervisors are expected to perform in a HACCP environment. The Blueprint contains six roles and three foundation principles. The six roles are: leader, evaluator/decision maker, communicator, program advocate, resource manager, and living example. The three foundation principles are: accountability, interpersonal relations, and innovation/creativity. When supervisors are carrying out the roles that are outlined in the Blueprint, the supervisor will be leading change in that they will be working “on” the system rather than “in” the system in a proactive rather than a reactive way. They will be using a systems thinking process which enables them to become critical thinkers, problem solvers, and effective decision makers who are accountable for their own actions.

Previously, two supervisory guides (the Supervisory Guideline for the Evaluation Process of the SSOP Regulatory Requirement, and the Supervisory Guideline for the Verification and Enforcement Process of the SSOP Regulatory Requirement) were issued. This guide represents a continuation of the earlier issued guides in that it describes how supervisors can apply the roles and foundation principles proposed in the Blueprint to work “on” the system in a proactive way

while overseeing the implementation of the Pathogen Reduction/HACCP requirements. It covers all of the requirements: HACCP, SSOP, *E. coli* sampling, and *Salmonella* sampling.

III. APPLICATION

A. Preparing for implementation of all Pathogen Reduction/HACCP regulatory requirements

The important role of supervisors in the process of implementing the Pathogen Reduction/HACCP requirements, which actually began in January of 1997, with the implementation of the SSOP requirements, and continues as large establishments must implement HACCP requirements. There are four key functions that will occur as part of the pre-implementation phase. They include the HACCP training, plant level awareness meetings, updating plant profiles, and establishment/shift procedure planning and work assignment. The supervisor has an important role in overseeing all of these pre-implementation functions. Some key points about each of the four pre-implementation functions follow.

1. **HACCP training:** HACCP training for inspection personnel assigned to large establishments began on December 1, 1997. Before inspection personnel perform HACCP procedures, it is essential that they have received the HACCP training. The training covers how to regulate in a HACCP environment. Communication is essential to insuring that the work force has a full understanding of the HACCP requirements. Once inspection personnel have completed the training, supervisors should have open dialogue and be ready to answer any questions inspection personnel may have about the HACCP requirements and the related inspection procedures. For example, it is important that inspection personnel understand the concepts of a

critical control point (CCP) and a critical limit, the differences between basic compliance/noncompliance and the other compliance/noncompliance procedures and how to conduct those procedures, how to use the basic compliance/noncompliance checklists and how to document noncompliance on a Noncompliance Record (NR), etc. When needed, the dialogue can be extended to plant management officials. **Directives 5000.1, 5400.5, the HACCP Regulatory Process for HACCP-Based Inspection Reference Guide, and the training materials will be useful references** for supervisors and inspection personnel in finding answers to questions. **If assistance is needed in answering questions, follow the instructions that were given in Module 10 of the HACCP training on contacting the Technical Service Center.**

2. Plant awareness meeting: Since HACCP plans are plant-specific, inspection personnel cannot effectively perform HACCP procedures until they understand the establishment's HACCP plan. The plant awareness meeting provides an opportunity for inspection personnel to become familiar with the plan. Details on conducting this meeting can be found in Module 7 page 2 of the Participant's Handout in the HACCP training materials. To summarize, the IIC will take the lead in planning for and being responsible for holding the meeting. The IIC may want to request an opportunity to review the establishment's HACCP plan before holding the awareness meeting to help in planning how much time will be needed and who should be involved. **It is important to remember that, like the SSOP, the HACCP plan is the property of the establishment.** However, it is a regulatory requirement for the plan to be made available to inspection personnel for all shifts. **It is also important for all inspection personnel to be aware that the awareness meeting does not represent FSIS approval of the**

establishment's HACCP plan. FSIS personnel will not be approving HACCP plans. Also, FSIS personnel will not be directing the establishment in the development of its HACCP plan in any way. **The purpose of the plant awareness meeting is for inspection personnel to become familiar with the establishment's plan.** The plant awareness meeting should cover the following topics: plant monitoring, plant verification, plant record keeping, plant pre-shipment procedures, plant corrective actions, and plant validation. **No regulatory determinations can be made until the plant awareness meeting has been completed.**

Discussion about the pre-shipment review will be an important part of the plant awareness meeting. The purpose of pre-shipment review is to ensure that establishment officials take responsibility, not only for developing a HACCP plan and being committed to implementing it, but also for making sure that it has been appropriately and completely applied in the production of product leaving the establishment. The requirement can be met in a variety of ways. During the plant awareness meeting, inspection personnel should become familiar with the procedures the establishment will use to conduct its pre-shipment review. They should also become familiar with how the establishment plans to define specific production.

While conducting the plant awareness meeting, FSIS participants should practice the six Relationship Principles covered in Module 11 of the HACCP training. The amount of time for the meeting will vary according to the size of the establishment and the complexity of the plans. It is expected that for large plants, the awareness meeting may take from one to four days. Inspection personnel who will perform the HACCP inspection procedures should participate in the meeting. **The IIC will be responsible for ensuring that appropriate inspection personnel on both**

shifts attend a plant awareness meeting. The time allocated for inspectors to participate may vary according to their area of responsibility in monitoring the HACCP plan. In processing assignments without an on-site supervisor, the IIC will communicate with the Circuit Supervisor to determine the amount of time to be spent on the awareness meeting. The planning for the awareness meeting should be done so that participation in the meeting does not interfere with an inspector's responsibility for carrying out the SSOP procedures or impact upon giving breaks to on-line inspection personnel. During the awareness meeting, inspection personnel should become familiar with the establishment's plan and how it addresses the 7 principles. The HACCP plan should contain at least one CCP for each food safety hazard identified as reasonably likely to occur in the production process. Inspection personnel should focus on understanding monitoring methods, frequencies, and who will be performing these duties; plant verification activities including monitoring oversight, calibration of equipment, and who is responsible for corrective actions; and **very important - understand pre-shipment review procedures.** They can also become familiar with issues such as where HACCP records will be kept, how to gain access to computer records, where CCPs are located, etc.

It is not necessary for the Circuit Supervisors to be familiar with HACCP plans for individual establishments at the operational level of detail that the IIC must be. However, functioning as a leader and communicator, the Circuit Supervisor should discuss with the IIC what was learned at the awareness meeting to become familiar with the general contents of the HACCP plan for each establishment (e.g., number and type of CCPs, how CCPs will be monitored by the establishment, where HACCP records are kept). Communication is essential to

insuring that the work force has a full understanding of the HACCP requirements. Supervisors should have open dialogue and be ready to answer any questions inspection personnel may have about the establishment's HACCP plan. If assistance is needed in answering questions, contact the Technical Service Center.

3. Updating plant profiles: The plant profile form has been modified to capture information about an establishment's HACCP system. As discussed in Module 6 on page 6 of the Participant's Handout in the HACCP training materials, **the IIC will be responsible for updating the plant profile** and sending it to the District Office. The directions for completing the revised plant profile form (5400-1) are provided in FSIS Directive 5400.5, Attachment 1. The general instructions for completing and maintaining the form have not changed. However, changes have been made so that information about the establishment's HACCP system can be recorded. For example, process activities in the data block were replaced by the nine HACCP processes. As leaders, communicators, and program advocates, supervisors should verify that plant profiles for large establishments have been updated and returned to the District Office in a timely manner. This should be done **sometime after the plant awareness meeting**. But, it is not required that it be done by the actual implementation date.

4. Establishment/Shift Procedure Plan and work assignment: The Establishment/Shift Monitoring Plan has been changed to the **Establishment/Shift Procedure Plan** for HACCP establishments. This is covered in Module 6 on pages 6-7 of the Participant's Handout of the HACCP training. To review the training, PBIS will create daily schedules based on the Establishment/Shift Procedure Plan. The procedures marked on the Inspection Procedure

Worksheet for the Establishment/Shift Procedure Plan must reflect plant operations conducted on each shift. This is different from the Monitoring Plans in non-HACCP plants that are created for each inspector assignment. In a HACCP plant, when multiple off-line inspectors are assigned to the same shift, they will share one single Procedure Plan. Procedure Plans will be generated for each shift, not for each inspector assignment. Establishments with more than one shift will have one Procedure Plan for each shift. For large establishments, the establishment/shift Procedure Plan was completed at Headquarters. Therefore, **the IIC will need to review the Procedure Plan and add or delete procedures based on what is known about the plant**, in case the information that the Headquarters staff used was outdated or incorrect, and return it to the District Office. In particular, the HACCP procedures recorded on the Procedure Plan should be consistent with the type of product(s) being produced by the establishment. All meat and poultry products fall into one of the nine HACCP processing categories in regulations 417.2(b). The final condition of a product when it leaves the establishment is the key to which particular HACCP procedure is marked on the worksheet. Complete instructions for developing, reviewing, and maintaining the Establishment/Shift Procedure Plans are in FSIS Directive 5400.5. They are basically the same as the instructions for developing, reviewing, and maintaining a Monitoring Plan. In addition to reviewing the Establishment/Shift Procedure Plans for HACCP implementation in January, the Directive indicates that the IIC or designee will review them at least annually and upon rotation to assure that there is a plan for every shift that reflects the operations that the establishment conducts during that shift.

Work assignment: As was covered in Module 6 of the HACCP training, the IIC will

continue to receive weekly schedules that identify the in-plant procedures to be performed each day in an establishment. The assigned procedures that appear on the schedules are randomly selected and will vary from day to day. The schedules for a HACCP assignment will be called **Procedures Schedules (PS)**, rather than Inspector Assignment Schedules. Only one PS will be issued per establishment, per shift. This means that the schedules will no longer be issued for individual inspection assignments. When the IIC is working with two or more inspectors, it will be necessary to identify who is going to do what procedure(s). **When dealing with assigning work related to the PS, supervisors should keep in mind some of the culture changes that are occurring as a result of the HACCP rule.** One change is that accountability and responsibility needs to be delegated to inspection personnel for given work assignments. Another culture change is that the expectations for the supervisory style of decision making are moving from an authoritative mode to a more participative/leader mode. Leadership and relationship tools and techniques for making these needed changes, including the Supervisory Blueprint and Blanchard's Situational Leadership Model of directing, coaching, supporting, and delegating, were covered in the Pre-HACCP and Culture Change Supervisory Training Program. It is important for supervisors to use these leadership and relationship tools and techniques when making work assignments using the PS. The work assignment is to be accomplished by the IIC and inspectors jointly reviewing and identifying the work to be done. In general, inspection personnel who handle off-line non-processing duties will continue to perform procedures associated with non-processing activities. Similarly, inspection personnel who perform processing duties will continue to perform procedures associated with processing activities. Once this has

been determined, if there are two or more non-processing or processing inspectors, the inspectors themselves will determine who will do what procedures. If for any reason they are unable to do so, the IIC will personally assign the procedures.

In terms of assigning **other work**, the first priority is the coverage of slaughter line positions. However, **it is important for supervisors to manage the process of assigning work so that it enables all inspection personnel to enhance their knowledge and understanding of the Pathogen Reduction and HACCP requirements and the regulatory process.** The other work includes assigning:

- a. Non-processing off-line inspectors to shadow the processing inspector doing HACCP verification on processes covering the simple processing area;
- b. Processing GS-8s and GS-9s to shadow the GS-10 or GS-11 processing inspector doing HACCP verification on processes covering the complex processing area;
- c. Inspection personnel to complete computer-based HACCP training programs available through the Human Resource Development Staff in College Station, Texas; and

- d. Off-line inspectors to cover slaughter line assignments.

Supervisors are responsible for using this opportunity for training to develop the HACCP-related skills of all inspection personnel. No employee should be idle. On-the-job training (OJT) should be documented.

B. Basic Compliance/Noncompliance

The concept of Basic Compliance/Noncompliance is covered in Modules 7 and 8 of the HACCP training, and in FSIS Directive 5000.1. As the Directive indicates, possible failures to comply with food safety-related regulations are divided into two categories: basic compliance/noncompliance and compliance/noncompliance with other requirements. To make a distinction, **basic compliance/noncompliance addresses the regulatory requirements that the establishment must include in the HACCP plan, while other features compliance/noncompliance is concerned with the actual day-to-day execution of those requirements.** This section addresses the supervisory considerations for basic compliance/noncompliance for the HACCP, SSOP, and *E. coli* requirements which includes the ISP procedures 03A01 for HACCP requirements, 01A01 for SSOP requirements, and 05A01 for *E. coli* requirements. Note that there is **not a basic procedure for *Salmonella* sampling.**

The purpose of the basic procedure is for inspection personnel to determine whether or not an establishment has complied with the requirements of developing and implementing plans/procedures outlined in FSIS Directive 5000.1. For each of these procedures, there is a **basic compliance checklist.** To review the training, the procedures are designed to be performed on an **unscheduled basis** at the **time of initial implementation**, and at

the discretion of inspection personnel, e.g. if **the plans are modified**. For HACCP requirements, the basic procedure will also be performed **annually** as an unscheduled procedure shortly after the anniversary date of implementation, even if the plan was revised some time during the year. This section provides supervisors with an overview of the regulatory requirements, discussion on the use of the checklists, and a review of enforcement actions related to the basic procedures.

The enforcement process is the same for all basic requirements. However, the enforcement process is reviewed for each case in this guide as a reference.

1. HACCP basic procedures:

a. Regulatory requirements for HACCP basic procedures: The establishment has the responsibility for developing and implementing a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more hazards that are reasonably likely to occur. A single HACCP plan may include multiple products within a single processing category if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed are essentially the same, and if any features of the plan that are unique to a specific product are clearly addressed in the plan and observed in its practice. The regulatory requirements ensure that the establishment's plan covers the 7 principles of HACCP. Every supervisor and employee should be familiar with the requirements in advance of the implementation date. The requirements as outlined in FSIS Directive 5000.1 follow.

Hazard Analysis and HACCP Plan development

- ▶ Initial hazard analysis. The establishment conducted a **hazard analysis** or had a hazard analysis conducted for it (§417.2(a)). (1) The hazard analysis includes food safety hazards that are reasonably likely to occur in the production process (before, during, and after entry into the establishment) and (when there are any) it identifies the **preventive measures** the establishment can apply to those food safety hazard(s). (2) The hazard analysis includes a **flow chart** that describes (diagrams) the steps of each process and product flow in the establishment. (3) The hazard analysis identifies the **intended use or consumers** of the finished product(s).
- ▶ Initial plan development. (1) If an establishment's hazard analysis revealed one or more food safety hazards that are reasonably likely to occur, the establishment has a **written HACCP plan for each of its products** (at the time commercial production begins) (§417.2(b)(1); §304.3(c) or §381.22(c)). (A HACCP plan must be developed by an individual who satisfies the training requirements in §417.7(b) (§417.7(a)(1)); see Paragraph III.B.3c. of this part.) (Note: It is possible, though unlikely, that a hazard analysis conducted in accordance with §417.2(a) will reveal no food safety hazards that are reasonably likely to occur. FSIS is not aware of any meat or poultry production process that one can say, categorically, poses no likely hazards.) (2) The establishment has conducted **validation activities** to determine that a HACCP plan is functioning as intended, and the establishment's records (a) include **multiple results** that **verify the monitoring of CCPs and conformance with critical limits**, and (b) after each deviation

from a critical limit (if any), subsequent results that support the adequacy of corrective action(s) in achieving control at the CCP (§417.2(c)(4), 417.3(a)(2), and 417.4(a)(1)).

- ▶ Subsequent analysis and plan development. (1) Hazard analysis reassessment. If, after an establishment's hazard analysis revealed no food safety hazards that are reasonably likely to occur, there was a change that could reasonably affect whether a food safety hazard exists, the establishment reassessed the adequacy of the hazard analysis (§417.4(b)). (Examples of changes that might have such an effect: raw materials or raw materials' source, product formulation, slaughter or processing methods or systems, production volume, personnel, packaging, finished product distribution system, or intended use or consumers of finished product.) (2) New product. Before producing a new product for distribution, the establishment (a) conducted a hazard analysis (or had a hazard analysis conducted for it), and (b) has an applicable HACCP plan for the product. If the establishment began distributing a new product more than 90 days ago, it has validated the HACCP plan that covers the new product.

Contents of the HACCP plan(s)

- ▶ Multiple products. If a HACCP plan covers more than one product, the products are all within one of the nine processing categories specified in §417.2(b)(1) (§417.2(b)(2)).
- ▶ Food safety hazard(s). The HACCP plan lists the **food safety hazard(s)** identified in the hazard analysis (§417.2(c)(1)). (These are the food safety hazards that must be controlled for each process.) **Exception:** A HACCP plan for **thermally processed/commercially sterile products** produced in accordance with part 318, subpart

G, or part 381, subpart X need **not address food safety hazards associated with microbiological contamination** (§417.2(b)(3)).

- ▶ Hazard control. (1) The HACCP plan list the **CCPs** for each food safety hazard (§417.2(c)(2)). (2) The HACCP plan lists the **critical limits** that must be met at each CCP (§417.2(c)(3)).
- ▶ Monitoring. The HACCP plan lists the **procedures** to be used to monitor each CCP and the **frequency** with which these procedures will be performed (§417.2(c)(4)).
- ▶ Corrective actions. The HACCP plan identifies the **corrective action** to be followed in response to a deviation from a critical limit at a CCP (§417.2(c)(5)).
- ▶ Verification procedures. The HACCP plan lists the procedures that the establishment will use to **verify that the plan is being effectively implemented** and the **frequency** with which these procedures will be performed (§417.2(c)(7)).

Record keeping

- ▶ The HACCP plan's **record keeping system** documents the monitoring of CCPs and includes records with actual values and observations.

Dated signature

- ▶ Acceptance and reassessment. The responsible establishment official has **signed and dated** the HACCP plan (a) upon **initial acceptance** (§417.2(d)(1)), and (b) at least **annually** thereafter upon required plan reassessment (§417.4(a)(3)) (§417.2(d)(2)(i) and (d)(2)(iii)). (Note: To determine whether a year has elapsed, use the date on which the HACCP system regulations apply to an establishment.)

b. Use of the checklist to verify that HACCP Plans meet regulatory requirements: On January 26, 1998, the Pathogen Reduction/HACCP regulation will be implemented in large plants. Inspection personnel will **conduct 03A01 as an unscheduled compliance/noncompliance procedure** to determine if the establishment's HACCP plan(s) meets regulatory requirements. **FSIS does not approve HACCP plans**, but inspection personnel will **use the HACCP Systems - Basic Compliance Checklist, FSIS Form 5000-1**, to assure that every HACCP plan has met the basic regulatory requirements. If a plant has several HACCP plans, inspection personnel will be required to use the checklist and perform the 03A01 procedure for each one of the plans. Inspection personnel will **document on a blank Procedure Schedule (PS)** that the 03A01 procedure was performed. **A trend indicator is not marked on the NR or PS** because the procedure code is specific to the basic compliance/noncompliance procedure.

Use of the checklist is covered in pages 6-7 of the Participant's Handout in Module 7 of the HACCP training. To review the training, the **checklist contains four basic parts**: (1) the establishment's hazard analysis and HACCP plan development, (2) the contents of the HACCP plan(s), (3) record keeping, and (4) a dated signature by the responsible establishment official. These 4 parts follow the requirements outlined in FSIS Directive 5000.1. If the establishment complies with all of the regulatory requirements, the establishment identifying information is completed at the top of Form 5000-1 and placed in the government file. If any of the basic regulatory requirements have not been met, the appropriate statement(s) on the checklist should be checked, "YES," and the noncompliance should be recorded on a **Noncompliance Record (NR)**. Note that there is no trend indicator for a basic noncompliance. Unless the noncompliance

can be effectively and immediately corrected by the establishment, inspection personnel should also initiate withholding action. Withholding inspection constitutes taking an enforcement action, and enforcement actions are covered in more detail in the next section of this guide (1.c.). **The District Office should be notified.** The completed checklist should be attached to the file copy of the NR when noncompliance is found.

Supervisors should have open dialogue and be ready to answer questions that inspection personnel have about completing the HACCP Systems - Basic Compliance Checklist. It is important to remember that before completing the checklist, inspection personnel must have **completed the plant awareness meeting.** Also, supervisors should ensure that inspection personnel understand that there are **three possible times for using the checklist.** First, inspection personnel will use the checklist soon after **the HACCP system regulations first apply to the establishment.** Another time that inspection personnel are required to use the checklist will follow **shortly after the establishment's anniversary for implementing the HACCP requirements,** once the establishment has conducted its required annual reassessment of the plan. A third opportunity for using the checklist will occur **at any point when the establishment revises its HACCP plan.** The establishment is not required to notify inspection personnel when they revise their plan(s), however, there are some cues that inspection personnel can use to help them identify when it is time to use the checklist between the implementation of the plan and the anniversary of its implementation. Some typical examples of these cues are: (1) the establishment begins producing a new product, (2) there are changes that could reasonably affect whether a hazard exists, (3) the procedures that the establishment identified in the plan are not controlling

the hazards that were identified in their plan, and (4) an unforeseen hazard occurs. (More details on unforeseen hazards are included in section C of this guide.)

c. Enforcement actions related to HACCP basic procedures:

Information about enforcement actions related to HACCP basic procedures are covered in pages 7-9 of the Participant's Handout in Module 7 of the HACCP training. To summarize, when inspection personnel find noncompliance with any of the basic HACCP requirements of the regulations, **withholding action** is warranted. There is one **exception**. Supervisors should advise inspection personnel that if the noncompliance with requirements only involves a failure that the responsible establishment official **can correct effectively and immediately** (e.g., sign and/or date the HACCP plan), inspection personnel will provide establishment management an opportunity to do so to bring the establishment into compliance. In this case, no withholding action is necessary, but the failure will be **documented on the NR** by inspection personnel with a statement that the situation was immediately corrected. However, if noncompliance involves a **failure that cannot be corrected effectively and immediately**, the IIC should take the following actions.

- ▶ **Advise the establishment management orally** of the findings on which the withholding action is based, and as soon as possible, **provide the establishment management with a copy of the NR** that documents noncompliance finding(s).
- ▶ **Withhold inspection**, which includes refusing to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as “inspected and passed” or “inspected for wholesomeness.”

- ▶ Identify all possibly adulterated livestock and/or poultry products as “**U.S. Retained.**”
- ▶ **Notify the District Office** of the action(s) taken.
- ▶ If the establishment does not initiate action immediately to bring itself into compliance, notify the District Office, which will assign a **Compliance Officer** to work with inspection personnel to develop a **case file**. The District Office will give inspection personnel **further instructions**. For example, the District Manager may place the withholding action **in abeyance**. In this case, the plant is required to provide **written assurances** that it will bring itself into compliance. This does not mean that the enforcement action has ended. If the plant fails to follow its written assurances and bring itself into compliance, the withholding action will be reinitiated.

Circuit Supervisors should exercise their role as program advocate and communicator to assure the **IIC** that he or she is **empowered** to contact the District Office directly when they take a withholding action. Because the FSIS tradition is to follow the chain of command, IICs may need some **encouragement** to do this. As communicator, supervisors should explain to inspection personnel that the purpose of having a Compliance Officer get involved, when warranted, is to work with inspection personnel as a team member to document a case. Supervisors should be proactive by working on the system in covering these points with inspection personnel and **correlating with them on methodology and procedures during IPPS visits** so that when a withholding action is taken, supervisors are confident that inspection personnel understand the regulatory requirements and how to apply them correctly. For example, when making plant visits, Circuit Supervisors can review completed checklists and NRs, and discuss with inspection

personnel the observations that were made, the documentation that exists, and information about any withholding action that occurred. If any boxes on the right column of the checklist have been checked “YES,” indicating that noncompliance was found, inspection personnel should have documented the findings on an NR. Unless the noncompliance with the requirement(s) involved a failure that the responsible establishment official could correct effectively and immediately (e.g., sign and/or date the HACCP plan), inspection personnel should have also initiated withholding action. If the noncompliance was corrected effectively and immediately by the establishment, the NR should have a statement explaining that the situation was corrected immediately. Inspection personnel need to remember to **document on a blank Procedure Schedule (PS)** that the 03A01 procedure was performed. The incidences of 03A01 procedures will be reflected in the MIS reports.

2. SSOP basic procedures:

a. Regulatory requirements for SSOP basic procedures: The

regulatory requirements for SSOP basic procedures **remain the same** as they were in January 1997, when they were implemented for all establishments. They were reviewed during the HACCP training in Module 7. They are also covered in Part Three of FSIS Directive 5000.1.

They are:

- ▶ Sanitation SOPs. (a) *The establishment has **written Sanitation SOPs** that describe the procedures the establishment conducts **daily to prevent direct contamination or adulteration of product(s)** (§416.12(a)). (These procedures must be sufficient to prevent direct contamination or adulteration of product(s); see Paragraph III.B.2. of this part.)*

- (b) *The Sanitation SOPs identify which of the procedures are **pre-operational** procedures (§416.12(c)).* (c) *The pre-operational procedures address at a minimum the **cleaning of food contact surfaces of facilities, equipment, and utensils** (§416.12(c)).*
- (d) *The Sanitation SOPs specify the **frequency** with which the establishment will conduct each procedure (§416.12(d)).* (e) *The Sanitation SOPs identify the establishment **employee or employees responsible** for implementing and maintaining specified procedures (§416.12(d)).*
- ▶ *Record keeping. The establishment has identified records that, on a daily basis, document implementation and monitoring of the Sanitation SOPs and any corrective actions taken (§416.16(a)).*
 - ▶ *Dated signature. The individual with overall authority on-site or a higher level official of the establishment has signed and dated the Sanitation SOPs (a) upon initial implementation, and (b) upon any modification (§416.12(b)).*

Supervisors should have open dialogue with inspection personnel to be sure that each of these five requirements is understood. It is important to remember that the SSOPs should describe the procedures the establishment conducts daily to prevent direct contamination or adulteration of product.

b. Use of checklists to verify that the establishment's SSOPs meet regulatory requirements: A **checklist (FSIS Form 5000-2)** has been developed for inspection personnel to use in recording findings of noncompliance with the SSOP requirements. A copy of this form is shown in FSIS Directive 5000.1. Use of the checklist is covered in Module 7 of the

HACCP training on pages 10-11 of the Participant's Handout. The **ISG task 02D01a2** is **replaced with the ISP procedure 01A01** for establishments that come under the HACCP regulations. Procedure 01A01 should be performed and the checklist should be used whenever modifications are made to the SSOPs. If the establishment complies with all of the regulatory requirements, the establishment identifying information is completed at the top of Form 5000-2 and it is placed in the government file. If any of the basic regulatory requirements have not been met, the appropriate statement(s) on the checklist should be checked, "YES," and the noncompliance should be recorded on a **Noncompliance Record (NR)** and appropriate enforcement action should be taken. Note that there is no trend indicator for basic noncompliance. Inspection personnel need to remember to **document on a blank procedure schedule** that the 01A01 procedure was performed. **The District Office should be notified.**

Supervisors should demonstrate their role as communicator to be sure that inspection personnel understand **when to use this checklist** in performing the procedure 01A01. The ISP procedure 01A01 does **not** need to be performed just because HACCP is being implemented. However, it should be performed and the checklist should be used **whenever modifications are made to the SSOP**. Inspection personnel need to remember to **document on a blank procedure schedule (PS)** that the 01A01 procedure was performed. This will be reflected in the MIS reports.

c. Enforcement actions related to SSOP basic procedures: When SSOP basic noncompliance occurs, inspection personnel will use the same process as for HACCP basic noncompliance. The process is repeated for reference purposes.

Information about enforcement actions related to SSOP basic procedures are covered in pages 10-11 of the Participant's Handout in Module 7 of the HACCP training. To summarize, when inspection personnel find noncompliance with any of the basic SSOP requirements of the regulations, **withholding action** is warranted. There is one **exception**. Supervisors should advise inspection personnel that if the noncompliance with requirements only involves a failure that the responsible establishment official **can correct effectively and immediately** (e.g., sign and/or date the SSOP), inspection personnel will provide establishment management an opportunity to do so to bring the establishment into compliance. No withholding action is necessary, but the failure will be **documented on the NR** by inspection personnel with a statement that the situation was immediately corrected. However, if noncompliance involves a failure that cannot be corrected effectively and immediately, the IIC should take the following actions.

- ▶ **Advise the establishment management orally** of the findings on which the withholding action is based, and as soon as possible, **provide the establishment management with a copy of the NR** that documents noncompliance finding(s).
- ▶ **Withhold inspection**, which includes refusing to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as “inspected and passed” or “inspected for wholesomeness.”
- ▶ Identify all possibly adulterated livestock and/or poultry products as **“U.S. Retained.”**
- ▶ Identify violative equipment, utensils, rooms, or compartments as **“U.S. Rejected.”**
- ▶ **Notify the District Office** of the action(s) taken.

- ▶ If the establishment does not initiate action immediately to bring itself into compliance, notify the District Office, which will assign a **Compliance Officer** to work with inspection personnel to develop a **case file**. The District Office will give inspection personnel **further instructions**. For example, the District Manager may place the withholding action **in abeyance**. In this case, the plant is required to provide **written assurances** that it will bring itself into compliance. This does not mean that the enforcement action has ended. If the plant fails to follow its written assurances and bring itself into compliance, the withholding action will be reinitiated.

Just as for HACCP basic requirements, Circuit Supervisors should exercise their role as program advocate and communicator to assure the **IIC** that he or she is **empowered** to contact the District Office directly when they take a withholding action. Again, because the FSIS tradition is to follow the chain of command, IICs may need some **encouragement** to do this. As communicator, supervisors should explain to inspection personnel that the purpose of having a Compliance Officer get involved, when warranted, is to work with inspection personnel as a team member to document a case. Supervisors should be proactive by working on the system in covering these points with inspection personnel and **correlating with them on methodology and procedures during IPPS visits** so that when a withholding action is taken, supervisors are confident that inspection personnel understand the regulatory requirements and how to apply them correctly. For example, when making plant visits, Circuit Supervisors can review completed checklists and NRs, and discuss with inspection personnel the observations that were made, the documentation that exists, and information about any withholding action that occurred. If any

boxes on the right column of the checklist have been checked “YES,” indicating that noncompliance was found, inspection personnel should have documented the findings on an NR. Unless the noncompliance with the requirement(s) involved a failure that the responsible establishment official could correct effectively and immediately (e.g., sign and/or date the SSOP), inspection personnel should have also initiated withholding action. If the noncompliance was corrected effectively and immediately by the establishment, the NR should have a statement explaining that the situation was corrected immediately.

3. *E. coli* basic procedures:

a. Review of regulatory requirements for *E. coli* basic procedures:

Details about the regulatory requirements for *E. coli* testing are covered in Modules 4a and 8 of the HACCP training materials and in Part Four, Paragraph II.B. of FSIS Directive 5000.1. To familiarize industry with the sampling guidelines, the Agency produced two videos which have been distributed to trade groups, and two booklets, “Guidelines for *E. coli* Testing for Process Control Verification in Cattle and Swine Slaughter Establishments,” and, “Guidelines for *E. coli* Testing for Process Control Verification in Poultry Slaughter Establishments,” which have been made available to establishments. Establishments are required to maintain sanitary conditions and use good manufacturing practices to avoid contamination of carcasses with visible feces and ingesta and associated bacteria. Fecal contamination is one of the major sources of pathogenic organisms that contaminate carcasses. The single best indicator of fecal and ingesta contamination is generic *E. coli* because it is commonly found in the intestinal tract of animals. According to the final rule on Pathogen Reduction/HACCP Systems, as of August 1997,

establishments that slaughter all market classes of **cattle, swine, chickens, and/or turkeys** are **required** to have a **written program** for conducting testing of carcasses for generic *E. coli*. The requirements which are addressed in FSIS Directive 5000.1 follow.

- ▶ Sampling procedures. (a) *The establishment has **written procedures** for collecting samples for *E. coli* testing.* (b) *The establishment's procedures identify the establishment employee(s) designated to collect samples for *E. coli* testing.* (c) *The establishment's procedures address (1) the **location(s)** of sampling, (2) how **sampling randomness** is achieved, and (3) **handing of samples** to ensure **sample integrity** (Paragraph (a)(2)(I) of §310.25 or §381.94).*
- ▶ Sample collection. *The establishment collects samples for *E. coli* testing (Paragraph (a)(1) of §310.25 or §381.94). (Note: An establishment that slaughters more than one type of livestock or poultry or slaughters both livestock and poultry must test for *E. coli* in the type that it slaughters in the greatest number.)*
- ▶ Record keeping. *The establishment records the analytical results of *E. coli* tests on a process control chart or table (Paragraphs (a)(1) (iii) and (a)(4) of §310.25 or §381.94).*

Plant employees must **conduct the testing**. **FSIS employees** will **oversee** the plant's testing program, but will not conduct the *E. coli* testing themselves. *E. coli* testing by slaughter establishments is a verification activity designed to **supplement** the FSIS organoleptic inspection and the establishment's physical removal of visible contamination. The test results are an indicator of sanitary dressing **process control** in slaughter establishments. *E. coli* results are compared to available **performance criteria** developed by the Agency from results of its

microbiological baseline studies. When performance criteria are not available for the type of sampling that the establishment chooses to use, the establishments must use **statistical process control** to **evaluate their test results**. The establishment will essentially conduct its own baseline study and set its own acceptable range and upper control limit. If the establishment's test results stay within the control limits set by the establishment, the process is considered to be in control. The performance criteria were designed to help each establishment determine whether its process control methods to reduce carcass contamination with feces and ingesta are effective. The baseline studies are conducted based on species and sampling method. In preparation for implementation of the Pathogen Reduction/HACCP regulation, the Agency developed performance criteria for the excision method of sampling for cattle and swine, and for whole bird rinse sampling of chicken. The table on the next page provides more information.

The *E. coli* performance criteria are **not enforceable regulatory standards**. Test results that show an establishment is meeting or exceeding the criteria provide evidence that the establishment is maintaining adequate process control for fecal contamination. Based on feedback from industry during the comment period on the proposed regulation, establishments are permitted to use sponging as a method for sampling the carcasses of cattle, swine, and turkeys. This is a less destructive method of sampling. The Agency is continuing to collect baseline data to develop performance criteria to address the sponging method. FSIS will also continue conducting tests to update the existing performance criteria.

Requirements for *E. coli* Sampling

	<u>Cattle</u>	<u>Swine</u>	<u>Chickens</u>	<u>Turkeys</u>
greater than very low volume - implemented 1-27-97	slaughter more than 6,000 sample size 1 in 300* carcasses	slaughter more than 20,000 sample size 1 in 1,000* carcasses	slaughter more than 440,000 sample size 1 in 22,000* carcasses	slaughter more than 60,000 sample size 1 in 3,000* carcasses
very low volume - implemented after 6-1-97	slaughter less than 6,000 sample size for all very low volume establishments is once per week (when slaughtering the species), up to the point when 13 consecutive samples meet the requirements	slaughter less than 20,000	slaughter less than 440,000	slaughter less than 60,000
method to evaluate testing results for all sizes of establishments	excision (m/M) or sponging (SPC**)	excision (m/M) or sponging (SPC)	whole bird rinse only (m/M)	whole bird rinse or sponging (both SPC)

*Or minimum of once per week, whichever is greater.

**statistical process control

Notes:

1. Plants slaughtering 50 or fewer animals per year will sample no more than 25% of the carcasses.
2. Exception: Establishments with validated HACCP plans may substitute an alternative frequency only if this frequency is already part of the establishment's HACCP verification procedures.
3. The **little m** represents the marginal range of test results, or those within the worst 20% of overall industry performance for *E. coli* counts. **More than 3 marginal results in the last 13 tests is unacceptable and warrants corrective action on the part of the establishment.**
4. The **big M** represents the unacceptable limit of test results, or *E. coli* counts higher than 98% of the establishments in the national baseline study. **Any single *E. coli* result exceeding the big M is unacceptable and warrants corrective action on the part of the establishment.**

Supervisors should have open dialogue with inspection personnel to be sure that inspection personnel understand that the *E. coli* performance criteria are **not enforceable regulatory standards**. There are several technical issues that supervisors should be sure inspection personnel understand. One is that **carcasses** that are selected for testing by plant employees must be **whole and intact**, not trimmed. For example, for poultry sampling, the location should be at an area at the end of the drip line after chilling and before packing and cut-up. One exception is hot-boned turkeys. Because they are boned before chilling, they should be sampled by the plant after the final wash. Although FSIS employees do not take *E. coli* samples, it is helpful for them to be familiar with the sampling methods (e.g., excision, sponging, whole bird rinse). Inspection personnel must understand that it is acceptable for the establishment to use an **in-house laboratory**, or they may ship samples to an outside laboratory to analyze results, as long as the analytical **method** is approved and published by a scientific body, such as the **Official Methods of Analysis of AOAC International**. Inspection personnel should also be aware that the establishment is **not required to maintain a file of laboratory results**. They are only required to keep a table or chart showing the results. Supervisors may want to review with inspection personnel to discuss their understanding of how to read and interpret **statistical process control charts**. For examples, see the Participant's Handout of Module 4a of the HACCP training material. Inspection personnel need to be aware that the establishment is required to take **corrective action** to bring the process of sanitary dressing back into control **if the *E. coli* test results do not meet the performance criteria** (either m/M values set by the Agency or statistical process control values set by the establishment). However, the establishment

is **not required to document** their corrective actions.

b. Use of checklists to verify that *E. coli* plans meet regulatory requirements: If the special *E. coli* team has not already done so, inspection personnel will perform procedure 05A01 to determine the establishment's basic compliance/noncompliance with the *E. coli* requirements. They will use the *E. coli* Testing Basic Compliance Checklist, which is FSIS Form 5000-3 (shown in Directive 5000.1), when performing the procedure. The checklist covers sample procedures, sample collection, and record keeping. If the establishment complies with all of the regulatory requirements, the establishment identifying information is completed at the top of Form 5000-3 and placed in the government file. If any of the basic regulatory requirements have not been met, the appropriate statement(s) on the checklist should be checked, "YES," and the noncompliance should be recorded on a **Noncompliance Record (NR)** and appropriate enforcement action should be taken. Note that there is no trend indicator for basic noncompliance. Inspection personnel need to remember to **document on a blank procedure schedule (PS)** that the 05A01 procedure was performed. **The District Office should be notified.**

c. Enforcement actions related to *E. coli* basic procedures:
When *E. coli* basic noncompliance occurs, inspection personnel will use the same process as for HACCP basic noncompliance. The process is repeated below for reference purposes.

Information about enforcement actions related to *E. coli* basic procedures are covered on page 3 of the Participant's Handout in Module 8 of the HACCP training. To summarize, when inspection personnel find noncompliance with any of the basic *E. coli* requirements of the

regulations, **withholding action** is warranted. There is one **exception**. Supervisors should advise inspection personnel that if the noncompliance with requirements only involves a failure that the responsible establishment official **can correct effectively and immediately** (e.g., entering the name, title, or position of an employee designated to collect samples), inspection personnel will provide establishment management an opportunity to do so to bring the establishment into compliance. No withholding action is necessary, but the failure will be **documented on the NR** by inspection personnel with a statement that the situation was immediately corrected. However, if noncompliance involves a failure that cannot be corrected effectively and immediately, the IIC should take the following actions.

- ▶ **Advise the establishment management orally** of the findings on which the withholding action is based, and as soon as possible, **provide the establishment management with a copy of the NR** that documents noncompliance finding(s).
- ▶ **Withhold inspection**, which includes refusing to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as “inspected and passed” or “inspected for wholesomeness.”
- ▶ Identify all possibly adulterated livestock and/or poultry products as “**U.S. Retained.**”
- ▶ **Notify the District Office** of the action(s) taken.
- ▶ If the establishment does not initiate action immediately to bring itself into compliance, notify the District Office, which will assign a **Compliance Officer** to work with inspection personnel to develop a **case file**. The District Office will give inspection personnel **further instructions**. For example, the District Manager may place the withholding

action **in abeyance**. In this case, the plant is required to provide **written assurances** that it will bring itself into compliance. This does not mean that the enforcement action has ended. If the plant fails to follow its written assurances and bring itself into compliance, the withholding action will be reinitiated.

Just as for HACCP basic requirements, Circuit Supervisors should exercise their role as program advocate and communicator to assure the **IIC** that he or she is **empowered** to contact the District Office directly when they take a withholding action. Again, because the FSIS tradition is to follow the chain of command, IICs may need some **encouragement** to do this. As communicator, supervisors should explain to inspection personnel that the purpose of having a Compliance Officer get involved, when warranted, is to work with inspection personnel as a team member to document a case. Supervisors should be proactive by working on the system in covering these points with inspection personnel and **correlating with them on methodology and procedures during IPPS visits** so that when a withholding action is taken, supervisors are confident that inspection personnel understand the regulatory requirements and how to apply them correctly. For example, when making plant visits, Circuit Supervisors can review completed checklists and NRs, and discuss with inspection personnel the observations that were made, the documentation that exists, and information about any withholding action that occurred. If any boxes on the right column of the checklist have been checked “YES,” indicating that noncompliance was found, inspection personnel should have documented the findings on an NR. Unless the noncompliance with the requirement(s) involved a failure that the responsible establishment official could correct effectively and immediately (e.g., omitting the name/title of an

employee designated to collect samples in the written procedure), inspection personnel should have also initiated withholding action. If the noncompliance was corrected effectively and immediately by the establishment, the NR should have a statement explaining that the situation was corrected immediately.

C. Other Compliance/Noncompliance

After performing the basic compliance checks for the establishment's HACCP, SSOP, and *E. coli* sampling plans, inspection personnel focus on the day-to-day or ongoing operation of the establishment's system. They will make determinations about **whether or not the establishment's system prevents the production or shipment of adulterated product**. This is the Other Compliance/Noncompliance component of the Regulatory Oversight Model. The concept of Other Compliance/Noncompliance is covered in Modules 9a through 9d of the HACCP training, and in FSIS Directive 5000.1. It includes procedures that address the other features for **HACCP, SSOP, *E. coli*, *Salmonella*, and other consumer protection**. This section addresses the supervisory considerations for the Other procedures. The verification, documentation, and enforcement procedures to be followed when an inspector finds **fecal contamination** on product after the final rail in red meat or just prior to entering the chiller in poultry slaughter establishments is addressed immediately following the discussion on other consumer protection procedures.

1. **HACCP** - Industry is responsible for developing, implementing, and maintaining effective HACCP systems to assure food safety. The FSIS role is one of regulatory oversight. This section addresses how FSIS will conduct oversight of the day-to-day or ongoing

operation of the establishment's HACCP system.

a. **Other features** - There are 5 features of a HACCP system that establishments must address. These features are outlined in FSIS Directive 5000.1. They include monitoring, verification, record keeping, corrective action, and plan reassessment. The features as outlined in Directive 5000.1 follow.

- ▶ Establishment monitoring. (a) *The establishment is monitoring CCPs to ensure compliance with critical limits (§417.2(c)(4)).* (b) *Establishment records documenting the monitoring of CCPs include the recording of actual values (in terms of observations and times, temperatures, and/or other quantifiable limits in the HACCP plan (§417.2(c)(6) and 417.5(a)(3)).*
- ▶ Establishment verification. (a) *The establishment is verifying the implementation of its HACCP plan(s) by performing verification activities (§417.2(c)(7) and 417.4(a)(2)).* (b) *Establishment records documenting verification activities include (1) the calibration of process-monitoring instruments, and (2) actions taken in response to a deviation from a critical limit (including a deviation not covered by a specific corrective action in the HACCP plan) (§417.3(c) and 417.5(a)(3)).* (c) *If an establishment that slaughters cattle, swine, chickens, or turkeys has substituted an alternative frequency for the frequency of sampling for E. coli specified in §310.25(a)(2)(ii) or §381.94(a)(2)(iii), the alternative is an integral part of the establishment's verification procedures (Paragraph (a)(2)(iv) of §310.25 or §381.94; see Part Four, Paragraph III.B.1.d.).*
- ▶ Deviations from critical limits. (a) Corrective actions. (1) *The HACCP plan assigns*

responsibility for taking corrective action (by, for example, specifying the establishment personnel who will perform various activities)(§417.3(a)). (2) In response to a deviation from a critical limit for which a HACCP plan identifies the corrective action to be taken, the establishment followed the corrective action procedure(s) in the plan (§417.2(c)(5) and 417.3(a)). (3) The establishment's records document corrective action taken in response to a deviation from a critical limit, including procedures to identify and eliminate the cause of the deviation, bring the CCP under control, establish measures to prevent recurrence, and prevent distribution of product adulterated as a result of the deviation (§417.3(a) and (c) and 417.5(a)(3)). (b) Unforeseen hazards. In response to a deviation from a critical limit that a HACCP plan does not cover with a specific corrective action, the establishment's records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine the acceptability of affected product for distribution, and when necessary, took action to ensure that product adulterated as a result of the deviation would not be distributed (§417.3(b) and (c) and 417.5(a)(c)).

- ▶ Plan reassessment and modification. (a) Reassessment. (1) If a deviation that is not covered by a corrective action specified in a HACCP plan occurred, or another unforeseen hazard arose, the establishment reassessed the HACCP plan (§417.3(b)(4)). (2) If a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding the applicable performance standard (in Table 2 of §310.25(b)(1) or §381.94(b)(1)) on the second consecutive series of FSIS tests for that product, the

establishment reassessed the HACCP plan for that product (Paragraph (b)(3)(ii) of §310.25 or §381.94). (3) If there was a change that could affect the hazard analysis or alter a HACCP plan, the establishment reassessed the HACCP plan (§417.4(a)(3)). (b) Modification. If a plan reassessment revealed that a HACCP plan no longer meets the requirements in §417.2(c), the establishment modified the HACCP plan (§417.4(a)(3)). (c) Training. The individual who performed the reassessment or modification of a HACCP plan meets the training requirements in §417.7(b) (§417.3(b)(4), 417.4(a)(3), and 417.7(a)(2)).

- ▶ Records. (a) HACCP plan support. Establishment records (1) document the decision making associated with the selection and development of CCPs and critical limits, including references to the basis (scientific or technical and/or regulations) for each, and (2) support the monitoring and verification procedures that the establishment has selected and frequency with which the establishment conducts those procedures (§417.5(a)(2)). (b) Product identification. Establishment records document slaughter production lot, product code(s), product name, or other identifier (§417.5(a)(3)). (c) Authentication. Each entry on a record maintained under a HACCP plan is made at the time the specific event occurs, includes the date and time that the entry was recorded, and is signed or initialed by the establishment employee who made the entry (§417.5(b)). (Note: Any other record required by §417.5(a)(3) must include the date on which the record was made.) (d) Data integrity. The establishment has implemented controls to ensure data integrity for HACCP plan records maintained on computers (if any)

(§417.5(d)). (e) Records review. Prior to shipping a product for distribution, the establishment's review of the records associated with the product's production (to ensure completeness) includes (1) a determination that all critical limits were met, and (2) when appropriate, a determination that the establishment took corrective action(s), including the proper disposition of product (§417.5(c)). (Note: Where practicable, an individual who did not produce the records must conduct, date, and sign the review.) (f) Retention and availability. (1) The establishment retains records required by §417.5(a)(3) for at least the following periods: 1 year for slaughter activities and for refrigerated product; 2 years for product that is frozen, preserved, or shelf-stable (§417.5(e)(1)). (2) Records required by §417.5(a)(3) are on-site for at least six months, and are available within 24 hours of an FSIS employee's request if stored off-site after 6 months (§417.5(e)(2)).

b. Inspection procedures - There are only two "other requirements" procedures for each HACCP activity - the **03 ISP procedures** ending in **01 and 02**. The purpose of these procedures is to determine if the establishment meets the five features - monitoring, verification, record keeping, corrective actions, and reassessment. Because the establishment must continually conduct monitoring, verification, and record keeping activities, inspection personnel will routinely verify that the establishment has met the monitoring, verification, and record keeping features. Verification that the establishment has met the features for corrective action and plan reassessment will be performed by inspection personnel when there is a reason - or when there are deviations from critical limits, unforeseen hazards, or positive *Salmonella* results.

The 01 procedure is for reviewing a **random sample** of the regulatory features in operation. The 02 procedure looks at a **specific production**. Both of these procedures have a **review and observation** component and a **record keeping component**. Both can be used to verify each of the five HACCP features.

When performing an 01 procedure, inspection personnel will use the review and observation and/or record keeping component to verify any combination of the features randomly. It would be equally appropriate to focus on one of the features specifically while performing the 01 procedure. If noncompliance is found while performing the 01 procedure, it must be documented on a noncompliance record, and then the associated 02 procedure should be performed. Because the 01 procedure is random, it is making a determination if the establishment meets the HACCP features. The reason for proceeding to an 02 procedure is to look at the system for production from start to finish. The HACCP 02 procedure focuses on the system in operation by making the determination about whether the establishment is following its HACCP plan.

The 02 procedure is not random. It is used to verify all five of the features. The 02 procedure is not considered complete until after the establishment's pre-shipment review can be verified. Therefore, performing the 02 procedure may take some time, depending on the process. Because the 02 procedure looks at the entire process for specific production, it determines if the HACCP plan prevented distribution of adulterated product.

The following section discusses the inspection procedures that will be used to verify each of the five features.

- Monitoring - Inspection personnel perform both the 01 and 02 inspection procedures to verify that the establishment's monitoring features are met. Each of the two procedures has a review and observation component and a record keeping component. For review and observation, inspection personnel determine if the establishment's monitoring is performed as described in the HACCP plan. This includes determining that critical limits are monitored by establishment employees using the method and frequency specified in the HACCP plan. This can be done by directly observing plant employees performing the tasks as stated in the plan, and taking measurements to see if the values obtained by inspection personnel match those recorded by the establishment. For the record keeping procedure, inspection personnel will determine if the establishment recorded its tests or measurements at the required frequency, if all required data was recorded, if the data is accurate, if critical limits have been met, and if corrective action was taken when necessary. Determining compliance/noncompliance for the monitoring requirement will be done on a random basis when performing the 01 procedure. When inspectors perform the 02 procedure, the monitoring requirement for all CCPs of a specific production or shipment will be verified. If the establishment finds a deviation, the corrective actions requirements of their HACCP plan must be met. This should be a trigger mechanism for inspection personnel to verify the corrective action requirement. If noncompliance is found, the "monitoring" trend indicator should be marked on the NR and PS.
- Verification - The verification activities listed in the establishment's HACCP plan will dictate what inspection personnel will do when performing procedures for this

requirement. There are review and observation components and record keeping components for both the 01 and 02 procedures. For the review and observation component, inspection personnel will determine if the establishment's employees are performing verification as stated in the plan, at the specified frequency, and recording the results promptly. For the record keeping component, inspection personnel determine whether the establishment's employees are doing product testing, record reviews, and calibrations at the specified frequencies, and if corrective action is taken when necessary. If the establishment finds a deviation, the establishment must meet the corrective action in their HACCP plan. This should trigger inspection personnel to verify the corrective action feature. In addition to the 01 procedure being random, if the establishment has an alternate sampling plan for *E. coli*, it will be verified under the 01 procedure. The 02 procedure is for a specific production. If noncompliance is found, the "verification" trend indicator should be marked on the NR and PS.

- Record keeping - Records are any written or other recorded information, such as electronically stored data on a computer, that the establishment generates to document activities, conditions, test results, etc. Inspection personnel will be reviewing establishment records that document their monitoring of the critical limits for critical control points, any corrective actions taken, and the establishment's verification activities. When verifying the record keeping requirement, only the record keeping component of the procedures will be performed. No review or observation of operations is necessary. When inspection personnel review CCP monitoring records, verification records, and

corrective action records, they will determine if the following has been recorded: (a) the product name or identity, product code, or slaughter production lot; (b) the date and time of the monitoring activity, verification activity, or corrective action;

(c) the signature or initials of persons performing the monitoring activity, verification activity, or corrective action. For the 01 procedure, inspection personnel will verify the HACCP support, product identification, record authenticity, data integrity, and record retention and availability features. For the 02 procedure, inspection personnel will verify only the pre-shipment and data integrity features. If the establishment finds a deviation, the establishment must meet the corrective action features of their plan. This should trigger inspection personnel to verify the corrective action features of the establishment's HACCP plan. If noncompliance is found, the "record keeping" trend indicator should be marked on the NR and PS.

- Corrective action - Corrective action(s) will be reviewed to ensure that any critical limit deviations found during their CCP monitoring, verification activities, and/or pre-shipment review have been addressed, and that the corrective action was documented. For corrective action that results from a deviation from a critical limit, the review and observation component that is done when the establishment takes corrective action for deviations might be on-site tests or observations to verify the establishment has brought the critical control point under control. Or, it might be observing the plant's procedures for segregating affected product. The record keeping component will be to determine if the corrective actions conform to all four of the requirements outlined in section 417.3.

(Note: They are reviewed under “other features” in this section of the guide.) The corrective actions must be sufficient to restore control to the process and to ensure that no adulterated product is distributed. For corrective action that results from an unforeseen hazard, the review and observation component checks the adequacy of the establishment’s corrective action procedures. This would include observing the establishment’s procedure for segregating affected product. For the record keeping component, inspection personnel will verify that the procedures used by the establishment to ensure that adulterated product was not shipped are documented. If, while performing the 01 or 02 procedure, inspection personnel determine that the establishment had to take corrective action in response to an unforeseen hazard, this should be a trigger mechanism to verify the plan reassessment requirement. If noncompliance is found, the “corrective actions” trend indicator should be marked on the NR and PS.

- Plan reassessment - Establishments are required to reassess their HACCP plans when a deviation is not covered by a stated corrective action, when an unforeseen hazard deviation occurs, when there is a second consecutive positive *Salmonella* result for raw meat or poultry, or when any change affects the hazard analysis. The establishment must modify its HACCP plan any time reassessment shows the plan no longer meets the requirements. The individual who reassesses and modifies the plan must be HACCP trained. Reassessment triggered by an unforeseen hazard deviation or a second positive *Salmonella* result may provide an opportunity for inspection personnel to verify the establishment’s reassessment of its HACCP plan. If the unforeseen hazard is determined by the

establishment to be reasonably likely to occur, the establishment's hazard analysis and HACCP plan must be modified. If it is not likely to recur, plan modification is not required. Documentation of plan reassessment by establishment personnel is not required. Therefore, there is no record keeping component. For the review and observation component for either the 01 or 02 procedure, you may observe the establishment's reassessment of the plan. The District Office will give inspection personnel instructions on how to deal with positive *Salmonella* results. When reassessment triggers the establishment to modify its HACCP plan, inspection personnel will always perform the 03A01, basic compliance checks procedure. Although the establishment employee conducting the plan reassessment must meet training requirements, the establishment is not required to furnish evidence of the training.

Supervisors should exercise their roles as leader, communicator, and program advocate by correlating with inspection personnel to be sure that they understand **how to perform the review and observation component** and the **record keeping components** for HACCP procedures. For **review and observation**, inspectors will be performing on-site tests such as taking temperatures of product after cooking, temperatures of coolers or carcasses in coolers, temperatures of chill water, etc., to determine if the CCP as defined in the plan is under control and comparing inspection results to HACCP plan records. They will also be directly observing establishment employees performing activities such as taking temperatures, calibrating monitoring equipment, taking corrective action, etc., to determine if the plant is following the HACCP plan and recording measurements accurately and promptly.

For **reviewing record keeping**, inspection personnel need to understand that FSIS views record keeping as a serious matter with potentially grave implications if records are falsified or not properly maintained. Inspection personnel will need to understand how to conduct record reviews in an organized manner. They will need to be able to select the appropriate type and number of records. Inspectors should be able to determine by reviewing records if there is an isolated problem or if there is a problem that represents a pattern of noncompliance over time, and across product lines. The record keeping procedure includes verification of HACCP support, product identification, record authenticity, data integrity, and record retention and availability requirements.

Some of these procedures are new and unfamiliar to inspectors. If inspection personnel have questions about how to perform the review and observation procedures or the record keeping procedures, supervisors need to be prepared to provide **on-the-job training** to assist them. For questions about verifying HACCP support, contact the **Technical Service Center**. For questions about verifying record authenticity and data integrity, contact District Enforcement Operations officials in the District Office.

Supervisors should ensure that inspection personnel understand that they are to have **access to the HACCP plan and all records and procedures** required by the Pathogen Reduction/HACCP system regulation. However, copies of HACCP plans, verification documents, and day-to-day operating records will not be routinely submitted to FSIS. Therefore, inspectors should not possess establishment records.

Supervisors should have open dialogue with inspection personnel to be sure that they

understand the **difference between HACCP 01 procedure and 02 procedure**. The 01 procedure is random and is used to determine if the establishment meets the HACCP features. The 02 procedure is not random. It is used to verify all five of the features. Because the 02 procedure looks at the entire production or shipment, it determines if the HACCP plan prevented distribution of adulterated product. If an inspector finds noncompliance while conducting the 01 procedure, the 02 procedure must be performed. The reason for proceeding to an 02 procedure is to look at the system. The HACCP 02 procedure focuses on the system in operation by making the determination about whether the establishment is following its HACCP plan.

Plants are not required to reassess their plan for 417.3 (a). Supervisors should ensure that inspection personnel are verifying that all four requirements for corrective action procedures are being addressed by the establishment in its implementation and documentation. The establishment is required to take and document corrective action procedures that will (1) identify and eliminate the cause of the deviation, (2) bring the CCP under control, (3) prevent the recurrence of the deviation, and (4) prevent the distribution of product adulterated as a result of the deviation.

When there are unforeseen hazards, or when the District notifies inspectors regarding positive *Salmonella* results, the establishment must take and **document corrective actions and reassess their plan**. Inspection personnel should understand that **plan reassessment** does not always lead to plan modification. If an unforeseen hazard is judged by establishment personnel as not likely to occur, then the establishment's HACCP plan need not be modified to incorporate it. Also, there is no requirement for reassessment to be documented by the establishment. Therefore,

there is no record keeping component. If inspection personnel are aware that the HACCP plan is modified, inspection personnel can perform the **03A01 basic compliance check procedure**.

Supervisors need to have open dialogue with inspection personnel and ensure that they understand that the establishment has flexibility in deciding how to conduct the **pre-shipment review**. This requirement is intended to ensure that establishment officials take responsibility, not only for developing a HACCP plan and being committed to implementing it, but also for making sure it has been appropriately and completely applied in the production of product leaving the establishment. The requirement can be met by the establishment performing a record verification as described at any point after the completion of processing, but before shipping, i.e., at the end of the day of production, but before product goes into storage; during the time product is in storage, but before it is shipped; immediately before shipment as the shipment is being made up and shipping documents are being prepared. The requirement can be met by initiating checks for records' completeness earlier and accomplishing the review in stages. The establishment might perform their pre-shipment review at varying points in the process, even on a continuous basis. The regulations 417.5(3)(c) require the establishment to review the records associated with the production of product to ensure completeness, including documentation that all critical limits were met, and if appropriate, corrective actions taken. It is up to the establishment to determine at what point and how they will meet this requirement. Great variability is expected in how this requirement will be met. The review is required to be signed and dated. There is a variety of ways in which this can be done by the establishment.

Supervisors should confirm with inspection personnel that because zero tolerance for

visible fecal contamination has been identified by the Agency as a food safety hazard that is reasonably likely to occur in the production process, it should be addressed in the HACCP plans for slaughter establishments. These requirements can be addressed in a variety of ways. The Agency will continue its verification checks for zero tolerance in slaughter establishments at the same point in the process and at the same frequency that they are traditionally performed. This topic is discussed in more detail at the end of this section. Further information will be provided to inspection personnel in the form of directives on FSIS verification.

c. Determining compliance/noncompliance - Noncompliance is failure by the establishment to meet any HACCP regulatory requirement. Noncompliance exists when either the establishment is not implementing its HACCP plan, or when its HACCP plan fails to prevent the production and shipment of adulterated product. While verifying the five regulatory features, inspection personnel will determine if there is noncompliance. If noncompliance is found, the inspector will also determine if a system failure exists. To determine noncompliance, inspectors must use what is known for a fact and what is reasonable to assume. The decision making process includes assessing observations, analyzing facts, deciding which performance standards or regulatory requirements apply, and determining if noncompliance exists.

Noncompliance will be documented on an NR with the appropriate trend indicator marked. The **trend indicators** correlate with the five features. They are briefly discussed.

- Monitoring trend indicator - This trend indicator is used when the establishment fails to monitor as prescribed in its HACCP plan. Some examples of noncompliance that match this trend indicator are when the plant is not monitoring a critical limit at a CCP, the plant

is not monitoring at the stated frequency, the plant fails to record the actual or quantifiable values at critical limits at CCPs, or the plant is not following the procedure methodology for monitoring as stated in its plan.

- Verification trend indicator - This trend indicator is used when the establishment is not performing the verification activities described in its HACCP plan (e.g., product testing, record reviews, and calibrations at the specified frequencies). It is also used when an establishment is not following the alternative frequency for sampling of *E. coli* as described in its HACCP plan.
- Record keeping trend indicator - This trend indicator is used when there are problems with the establishment's record keeping. Some examples include HACCP records that are not signed and dated; the plant fails to record the results of its monitoring; the production code, lot or identity is missing; and the records are not maintained for the required time frames. It is also used when the establishment lacks documentation to support its HACCP plan or when the pre-shipment review has not been completed by the establishment. The establishment must make records available to inspection personnel on both shifts.
- Corrective action trend indicator - This trend indicator is used when the establishment does not take corrective action in response to a deviation from a critical limit, or the corrective action **does not meet the requirements outlined in 417.3**. It is also used when the establishment fails to meet the plan reassessment requirements.

If the establishment fails to meet any of the basic requirements, this is documented under 03A01, the basic procedure code. There is no trend indicator for the basic procedure.

Until an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an NR, the NR is “open.” Inspection personnel are to review the file of “open” NRs daily. When an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in the issuance of an NR, inspection personnel are to file the NR as “closed.” The IIC is to meet with establishment management weekly to discuss noncompliance findings (if any) and action(s) taken by the establishment to bring itself into compliance.

FSIS documentation must reflect any part of the establishment’s HACCP plan that is in noncompliance. For example, in some cases, inspectors may find that the establishment had a deviation from a critical limit at monitoring but discovered it during verification and took the corrective action outlined in its plan. Even though the HACCP plan was implemented effectively by the establishment, the monitoring noncompliance would be documented on an NR. It is important to document the noncompliance in this case as a means of **documenting trends**. Trends are important in determining if the system has failed. Inspection personnel must also **allow the opportunity for the establishment’s HACCP plan to work**. In the example above, when the inspector measured the critical limit and found that it was exceeded, part of the 01 procedure would include returning after the next monitoring check to observe the establishment’s verification activities for that CCP.

Supervisors should be sure that if noncompliance is found, inspection personnel are determining if the system has failed. To determine if the **HACCP system is inadequate**, there are four questions to address. Each question is discussed below.

- Question 1 - Did the establishment review the records associated with the production of product? The review should have included a determination that all critical limits were met, and if appropriate, corrective actions were taken, including proper disposition of product. If the establishment has not performed the pre-shipment review, then it has not met the regulatory requirements (§417.5(c)). Therefore, inspection personnel are not able to make the determination that the establishment is not producing adulterated product, and the HACCP system is inadequate. This determination can only be made when performing the 02 procedure.
- Question 2 - Was adulterated product produced or shipped? If the establishment failed to meet a critical limit for a CCP and did not take the corrective action required by 417.3, and the establishment has performed its pre-shipment review, then the HACCP system is inadequate. This determination can only be made when performing the 02 procedure. However, the 02 procedure may have been performed in response to noncompliance found during the 01 procedure.
- Question 3 - Is there noncompliance with the same root cause? That is, are there the same and/or related noncompliance occurring due to negligence, ineffective method, or incomplete execution by the establishment? If yes, then it is possible that the system is inadequate. There is no “magic” number to determine when a systems failure exists due to the same and/or related noncompliance. This determination can be made when performing either the 01 or the 02 procedure. Inspection personnel should look at the noncompliance trend indicators on previously written NRs to make this determination. **The NRs should**

document ongoing failures of the establishment's maintenance or implementation of the HACCP plan and/or execution of effective and immediate and further planned actions to bring themselves back into regulatory compliance. Professional judgment is required when making this determination. If there is no evidence of noncompliance for the same root cause, or the evidence is weak, the noncompliance should be documented on the NR with the appropriate trend indicator marked.

- Question 4 - Has the establishment met the basic regulatory requirements? If the establishment is not implementing all or some of their program, then it has not met the basic regulatory requirements. Some examples are that the establishment is not maintaining records associated with its HACCP plan, or is not monitoring critical limits at a CCP, or not reassessing the HACCP plan when required. This determination can be made when performing either the 01 or the 02 procedure. When this occurs, inspection personnel are unable to determine that the establishment is not producing unadulterated product, and therefore the HACCP system is inadequate. Because this is a Basic noncompliance, it should be documented under the 03A01 Basic procedure code.

If inspection personnel determine that there is an inadequate HACCP system, enforcement action is taken.

Supervisors need to execute their role of communicator, evaluator, and program advocate to ascertain whether inspection personnel are using the appropriate decision making process in determining noncompliance. Supervisors will need to evaluate if inspection personnel are including what is known for a fact and what is reasonable to assume prior to determining noncompliance. It is also important to find out whether inspection personnel are providing the establishment with the opportunity to implement the HACCP plan.

A Noncompliance Record, or NR (FSIS Form 5400-4) serves as FSIS's official record of noncompliance with one or more regulatory requirements. Supervisors, in conjunction with inspection personnel, should **review NRs** and determine if the parameters in FSIS Directive 5400.5 are followed. The assessment of NRs should cover the following areas: selecting the appropriate trend indicator, describing the noncompliance on the NR, use of the NR Continuation Sheet, corrective actions and plant management's response to the issuance of an NR, and determining repetitive noncompliance. Each of these are discussed in the following pages.

(1) Supervisors will need to determine if inspection personnel are **selecting the appropriate trend indicator** to describe the noncompliance. The trend indicator should correspond with the regulatory requirement that is not met. If there are failures in more than one of the indicators, the one that is most appropriate should be marked on the PS and on the NR. For example, if the establishment monitor failed to detect a deviation from their critical limit for a CCP and did not catch the failure during its verification, but did find it during the pre-shipment

review and took appropriate corrective actions, both the monitoring and the verification features were not met. The most appropriate trend indicator to mark on the PS and NR would be the verification trend indicator. If however, there is evidence that the monitoring or the verification has taken place, but the establishment failed to document the monitoring or verification, then the record keeping trend indicator is used.

(2) Supervisors must assess whether inspection personnel **documentation in section 10** (Description of Noncompliance) of the NR creates a clear and accurate description of the noncompliance. The exact location in the establishment where the noncompliance finding was made should be included. The noncompliance should be described in objective terms. The information on the NR will form the basis of Agency administrative, civil, or criminal actions, therefore it is essential that it be clear and descriptive, allowing the reader to visualize the noncompliance. The NR must contain the provision(s) of the regulation(s) with which the establishment failed to comply as well as the page and/or part number of the establishment's HACCP plan that was not met. From an enforcement perspective, it is vital that previous noncompliance occurring as a result of the same and/or related negligence, ineffective methods or incomplete execution (i.e., root cause) be included in the documentation if warranted. This is discussed further in the following section.

(3) Supervisors must ensure that if additional space is used to describe noncompliance, an **NR Continuation Sheet** is attached. Just like NRs, Continuation Sheets must be written so that the reader can visualize the noncompliance. The NR Continuation Sheet must have the same number as the NR. The NR should indicate the number of Continuation Sheets that are attached.

All documentation will be provided to the plant manager.

(4) The NR contains a section for plant management's response. There are several areas for supervisors to correlate with inspection personnel concerning the plant management's response. Plant management's response should address immediate and further planned actions. The establishment may provide their response verbally. If the noncompliance is a deviation from a critical limit, the regulations require that the establishment take and document corrective actions as per 417.3.

(5) Supervisors must determine if inspection personnel are using the appropriate process to determine if a **systems failure** exists related to noncompliance. The four questions to ask are covered in previous part of this section. Professional analysis must be used when making this determination. **Inspection personnel must review previous NRs. The documentation must make a linkage to the previous noncompliance. If the NRs document ongoing failures of the establishment's maintenance or implementation of the HACCP plan and/or execution of effective and immediate and further planned actions to bring themselves back into regulatory compliance, inspection personnel should consider the establishment's system inadequate.**

d. Enforcement actions - If there is **noncompliance**, but it is **not** determined to be a **systems failure**, inspection personnel should take enforcement action according to Part III of FSIS Directive 5000.1 III.C.2. This includes:

- Taking official control action as appropriate;
- Advising establishment management by providing a copy of the NR that documents

noncompliance findings;

- Completing documentation of establishment action(s) to bring itself into compliance (see FSIS Directive 5400.5); and
- Notifying the District Office if the establishment does not bring itself into compliance.

If inspection personnel have determined that there is an **inadequate system**, they should follow the enforcement action in Part II of FSIS Directive 5000.1 II.C.1. This action is identical to the action that is taken if the establishment fails to meet the basic regulatory requirements. It is repeated below.

- ▶ **Advise the establishment management orally** of the findings on which the withholding action is based, and as soon as possible, **provide the establishment management with a copy of the NR** that documents noncompliance finding(s).
- ▶ **Withhold inspection**, which includes refusing to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as “inspected and passed” or “inspected for wholesomeness.”
- ▶ Identify all possibly adulterated livestock and/or poultry products as “**U.S. Retained.**”
- ▶ **Notify the District Office** of the action(s) taken.
- ▶ The District Office will assign a **Compliance Officer** to work with inspection personnel to develop a **case file**. The District Office will give inspection personnel **further instructions**. For example, the District Manager may place the withholding action **in abeyance**. In this case, the plant is required to provide **written assurances** that it will bring itself into compliance. This does not mean that the enforcement action has ended. If

the plant fails to follow its written assurances and bring itself into compliance, the withholding action will be reinitiated.

If there is a HACCP system failure involving the production or shipment of adulterated product in which misrepresentation of records is suspected, inspectors must withhold inspection and deal with the adulterated product first. Public health and safety will take precedence over any other activity. If at any time inspection personnel suspect that an establishment has engaged in any illegal activity (e.g., falsified required records; offered for sale, sold, or transported adulterated or misbranded meat and/or poultry products in commerce), they should report the alleged violations to the appropriate District Enforcement Operations official.

Circuit Supervisors should exercise their role as program advocate and communicator to assure the **IIC** that he or she is **empowered** to contact the District Office directly when they take a withholding action. Because the FSIS tradition is to follow the chain of command, IICs may need some **encouragement** to do this. As communicator, supervisors should explain to inspection personnel that the purpose of having a Compliance Officer get involved, when warranted, is to work with inspection personnel as a team member to document a case. Supervisors should be proactive by working on the system in covering these points with inspection personnel and **correlating with them on methodology and procedures during IPPS visits** so that when a withholding action is taken, supervisors are confident that inspection personnel understand the regulatory requirements and how to apply them correctly. For example, when making plant visits, Circuit Supervisors can review completed NRs, and discuss with inspection personnel the observations that were made, the documentation that exists, and

information about any withholding action that occurred.

2. SSOP - In January 1997, SSOPs were required in all official establishments. When HACCP is implemented, many SSOP-related aspects will remain the same. However, some will be different. For example, the regulatory requirements remain the same. However, when HACCP is implemented, inspection personnel will stop using FSIS Directive 11,100.3 and the old PBIS terms and start using **FSIS Directive 5000.1 (Part Three)** and the **new PBIS terminology** covered in FSIS Directive 5400.5. This was covered in HACCP training. To review, under the old PBIS system, the term “**evaluation**,” was used to describe the inspection task of determining if the establishment’s plan met regulatory requirements. Under HACCP, as was covered in section III., B, 2, of this Guide, the new term for determining if the plan meets the regulatory requirements is, “**Basic Compliance/Noncompliance**.” “**Verification**,” is called, “**Other Requirements Compliance/Noncompliance**,” in HACCP establishments. The classification of deficiencies using the Deficiency Classification Guide with documentation on PDRs will be discontinued. Instead, inspection personnel will document noncompliance using the Noncompliance Classification Indicator Guide on an **NR, or Noncompliance Record**. There is a comparison chart that shows the differences on page 14 of the Participant’s Handout in Module 9c of the HACCP training materials. This section of the Guide addresses the, “Other Requirements,” for SSOP-related activities (ISP procedures 01B01 and 01B02 for pre-operational sanitation and 01C01 and 01C02 for operational sanitation).

a. Other requirements - The four requirements for the SSOP are implementation (§ 416.13), maintenance or effectiveness of the SSOP - or monitoring (§ 416.14),

corrective actions (§ 416.15), and records (§ 416.16). Each of these are discussed briefly below.

- Sanitation SOP implementation. (a) *The establishment conducts pre-operational procedures before it begins operations (§ 416.13(a)).* (b) *The establishment conducts during-operations procedures at the frequencies in its Sanitation SOPs (§ 416.13(b)).* (c) *The establishment monitors daily the implementation of procedures in its Sanitation SOPs (§ 416.13(c)).*
- Corrective actions. *When (as determined by the establishment or by FSIS) the establishment's Sanitation SOPs -- or the procedures specified therein or their implementation or maintenance -- may have **failed to prevent direct product contamination or adulteration**, the establishment took appropriate corrective action(s), including procedures to (a) ensure the appropriate **disposition** of products that may be contaminated, (b) restore **sanitary conditions**, and (c) **prevent** the recurrence of direct product contamination or adulteration, including appropriate **reevaluation** and **modification** of Sanitation SOP procedure(s) or appropriate improvements in the execution of SSOP procedure(s) (§ 416.15).*
- Sanitation SOP Effectiveness. (a) *The establishment's Sanitation SOPs are sufficient to prevent direct contamination or adulteration of product(s) (§416.12(a)).* (b) *The establishment (1) routinely evaluates the effectiveness of the procedures in its Sanitation SOPs in preventing direct contamination or product adulteration, (2) **revises the procedures** in its Sanitation SOPs when necessary to keep them effective and current with respect to **changes in its facilities, equipment, utensils, operations, or personnel** (§*

416.14).

- Records. (a) Daily documentation. *The establishment's daily records document (1) implementation of its Sanitation SOPs, (2) monitoring of its Sanitation SOPs, and (3) corrective actions taken (if any) (§416.16(a)).* (b) Authentication. *The establishment's records must be **initialed and dated** by the establishment employee identified in the Sanitation SOPs as responsible for implementing and monitoring specified procedure(s) (§416.16(a)).* (c) Data integrity. *The establishment has implemented **controls** to ensure data integrity for part 416-required records maintained on computers (if any) (§416.16(b)).* (d) Retention and availability. (1) *The establishment **retains records** required by part 416 for at least 6 months.* (2) *Records required by part 416 -- are on-site for at least 48 hours, and are available within 24 hours of an FSIS employee's request if stored off-site after 48 hours (§416.16(c)).*

b. Inspection procedures - The way in which inspection personnel will need to perform in-plant SSOP verification has not changed. They will still perform **daily** procedures for **pre-operational** and **operational** sanitation inspection by either a **record keeping procedure** or a **review and observation procedure**. The record keeping procedure is for reviewing the daily documentation regarding the implementation of the SSOP and the corrective actions taken. The review and observation procedure is the same as the old "hands-on" verification task.

The inspector's performance of the review and observation procedure should include three parts: (1) direct observation of the establishment's implementation and monitoring of the SSOP

and required corrective actions; (2) assessment of sanitary conditions through organoleptic examination of a sample of facilities, utensils, and equipment; and (3) a comparison of inspection findings with plant records. By performing this procedure, inspection personnel will be verifying all four of the SSOP requirements (implementation, effectiveness, corrective actions, and record keeping). The methodology that is used to perform this procedure has not changed.

The record keeping procedure also covers all four requirements. The inspector's performance of the record keeping procedure must include: (1) verification that SSOPs are being followed by plant personnel before and during operations; (2) monitoring activities are conducted at the specified frequency; (3) all 3 requirements of corrective actions according to part 416.15 are implemented and documented as required; and (4) establishment employees/positions specified in the SSOP are assuming the implementation and monitoring of the SSOP by authenticating the records with their initials and date. Inspection personnel must also verify that the establishment has implemented controls to ensure data integrity for computer records (e.g., individual digital signatures, identification passwords), and that records are accessible, completed and made available within realistic time frames.

Supervisors should exercise their roles as leader, communicator, and program advocate by determining whether inspection personnel are employing the methodology defined in FSIS Directive 5000.1. Processing and import inspection personnel should be sampling equipment and facilities as they did prior to SSOP implementation. Slaughter inspection personnel should be following the methodology described in Appendix A to FSIS Directive 5000.1 (which is identical to the instructions for slaughter personnel in Directive 11,100.3). Slaughter inspection personnel

should NOT be expanding samples, rejecting areas, restricting units, or inspection auxiliary areas during pre-operational inspection. These procedures were eliminated with the cancellation of Directives 11,040.1 and 11,040.2.

Supervisors should verify that inspection personnel are **performing all three components of the review and observation procedure**. Because inspection personnel are most familiar with the organoleptic sampling component, the tendency may exist for this part of the procedure to be favored and the other parts neglected (direct observation of the establishment's implementation and monitoring of SSOP procedures/corrective actions AND a comparison of inspection findings with plant records). Supervisors may need to provide some on-the-job training and/or correlation to inspection personnel who are uncertain about how to conduct the components that involve the direct observation of plant employees and comparison of findings with plant records. It should be made clear to employees that it is acceptable for inspection personnel to perform their review and observation procedure **at the same time** that the establishment is monitoring their pre-operational procedures. This provides inspection personnel an excellent opportunity to perform the observation component of the procedure. Supervisors should make sure that inspection personnel understand that if they find noncompliance while the establishment is still conducting their monitoring, that inspection personnel should allow the establishment the opportunity to conduct the procedures in their SSOP. During this time, the inspector could either compare his/her findings to this point with plant records, if available, or observe the establishment conducting their monitoring procedures. Regulatory actions, if any, would be based on information the inspector obtained from performing all three components of the review and observation procedure. If an

establishment routinely conducts all of its pre-operational sanitation activities before inspection personnel perform their pre-operational activities, leaving no scheduled time for inspectors to conduct the observation portion of the review and observation procedure for pre-operational sanitation, supervisors must coordinate with inspection personnel to schedule periodic overtime for inspection personnel to conduct the observation portion of the review and observation procedure for pre-operational sanitation.

Supervisors should also verify that inspection personnel are conducting the **record keeping procedure** appropriately. Because establishment record keeping was not emphasized in the past, supervisors may need to discuss the importance of conducting this procedure with inspection personnel. They can also review and correlate the performance of the procedure with inspection personnel using a representative sample of plant generated SSOP records. Supervisors should be prepared to point out to inspection personnel whether or not the records meet the requirements, which include verifying that SSOP procedures are being followed by plant personnel before and during operations; that monitoring activities are being conducted at the specified frequency in the SSOP; and that the appropriate corrective actions are being implemented. Note that establishments do not have to document every action taken provided that the corrective action is consistent with the procedures specified in the SSOP. For example, establishment personnel do not have to document the action when parts fall on the floor - as long as the procedures for handling parts falling on the floor are being implemented, maintained, and documented according to the SSOP. Supervisors can conduct a record check to verify that establishment employee/positions specified in the SSOP are authenticating records with their

initials and dates.

c. Determining compliance/noncompliance - Noncompliance is failure to meet any regulatory requirement. Noncompliance exists when the establishment isn't implementing their SSOP or when the SSOPs do not prevent direct contamination or adulteration of product. Inspection personnel use what is **known for a fact and what is reasonable to assume** in determining if noncompliance exists. The establishment must be given the opportunity to **implement their SSOP** before a determination is made regarding noncompliance. When inspection personnel make a determination that noncompliance exists, they must do two things: (1) mark the most appropriate **trend indicator** when they document the noncompliance on the **PS** and the **NR**; and (2) determine whether the noncompliance represents a **systems failure**.

One of four **trend indicators** must be selected to describe the noncompliance. These correspond with the four other SSOP requirements reviewed earlier.

- **Monitoring (maintenance)** - This trend indicator is marked when the establishment fails to routinely evaluate the effectiveness of the SSOP in preventing direct product contamination or adulteration (e.g., plant fails to update the SSOPs based on a change in operations).
- **Corrective action** - This trend indicator is marked when the plant fails to take all of the corrective actions required by section 416.15 of the regulations (e.g., plant corrective actions are not appropriate to restore sanitary conditions, or do not include measures to prevent recurrence of direct product contamination or adulteration).
- **Record keeping** - This indicator is marked when records required by the SSOP are not

maintained (e.g., plant does not initial/date records, does not maintain records daily, does not retain them for the required period of 6 months, or fails to record the results of a monitoring check). If the plant fails to maintain any records at all, the results of the procedure would be documented as 01A01, basic noncompliance.

- **Implementation** - This indicator is marked when the plant fails to perform pre-operational sanitation inspection after equipment is cleaned and sanitized prior to operation, fails to perform operational sanitation inspection, or is not monitoring sanitation activities at the frequency stated in the SSOP. The implementation trend indicator is also used when noncompliance involves more than one trend indicator (e.g., record keeping and corrective action).

Until an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an NR, the NR is “open.” Inspection personnel are to review the file of “open” NRs daily. When an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in the issuance of an NR, inspection personnel are to file the NR as “closed.” The IIC is to meet with establishment management weekly to discuss noncompliance findings (if any) and action(s) taken by the establishment to bring itself into compliance.

The next decision is whether there has been a systems failure. There are 2 questions to ask. The first question is, “Was adulterated product produced?” If yes, this is a design or execution failure of the SSOP, but it is not a systems failure at this point. To determine that there is a systems failure, there must be a “yes” to the second question. The second question is, “Is

there noncompliance with the same root cause?” Inspection personnel will need to examine previous NRs and PDRs and analyze the trend indicators to make this determination. Are there the same and/or related noncompliances due to negligence, ineffective method, or incomplete execution by the establishment? If the NRs and PDRs document ongoing failures of the establishment’s maintenance or implementation of the SSOP and/or **execution of effective immediate and further planned actions to bring themselves back into regulatory compliance and the documentation makes the linkage to previous noncompliance, there is a systems failure.**

For **supervisors**, part of determining whether inspection personnel are employing the methodology defined in FSIS Directive 5000.1 is ascertaining whether inspection personnel are using the appropriate decision making process in determining noncompliance. Supervisors will need to evaluate if inspection personnel are including what is **known for a fact and what is reasonable to assume** prior to determining noncompliance. It is also important to find out whether inspection personnel are **providing the establishment with the opportunity to implement the SSOP** before identifying noncompliance.

A Noncompliance Record, or NR, (FSIS Form 5400-4) serves as FSIS’s official record of noncompliance with one or more of the SSOP requirements. Supervisors, in conjunction with inspection personnel, should **review NRs** and determine if the parameters in FSIS Directive 5400.5 are being followed. The assessment of NRs should cover the following areas: selecting the appropriate trend indicator, describing the noncompliance on the NR, use of the NR Continuation Sheet, corrective actions and plant management’s response to the issuance of an

NR, and determining repetitive noncompliance. These are discussed in the following pages.

(1) Supervisors will need to determine if inspection personnel are **selecting the appropriate trend indicator** to describe the noncompliance. For example, if there are failures in more than one of the indicators, the implementation trend indicator should be marked on the PS and on the NR. The trend indicators correspond with the other features. When there is no evidence that monitoring of implementation or corrective actions were performed by the establishment because there is no documentation, then the implementation or corrective action trend indicator would be selected as the most appropriate trend indicator. If, however, there is evidence that the monitoring of implementation or the corrective action has been taken, but the establishment failed to document it, then the record keeping trend indicator should be used.

(2) Supervisors must assess whether inspection personnel **documentation in section 10** (Description of Noncompliance) of the NR creates a clear and accurate description of the noncompliance. The exact location in the establishment where the noncompliance finding was made should be included. The noncompliance should be described in objective terms. The information on the NR will form the basis of Agency administrative, civil, or criminal actions, therefore it is essential that it be clear and descriptive, allowing the reader to visualize the noncompliance. The NR must contain the provision(s) of the regulation(s) with which the establishment failed to comply as well as the section or page of the establishment's SSOP procedures not followed. Previous noncompliance for the same root cause should be included in the documentation if warranted. **Also, the failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration as documented**

previously should be included. These issues are discussed further in the following section.

(3) Supervisors must ensure that when necessary, **NR Continuation Sheets** are used appropriately. When multiple inspectors perform an SSOP procedure, each inspector will document their individual findings. This can be accomplished by one inspector, as consulted at the local level, documenting on the NR, while the remaining inspector(s) utilize an NR Continuation Sheet for documentation purposes. All noncompliance with requirements must be documented. Just like NRs, Continuation Sheets must be written so that the reader can visualize the noncompliance. It must contain the provision(s) of the regulation(s) with which the establishment failed to comply as well as the section or page of the establishment's SSOP procedures not followed. Previous noncompliance for the same root cause should be included in the documentation if warranted. Also, the failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration as documented previously should be included. The NR Continuation Sheet must have the same number as the NR. The NR should indicate the number of Continuation Sheets that are attached. All documentation will be provided to the plant manager.

(4) The NR contains a section for plant management's response. There are several areas for supervisors to correlate with inspection personnel concerning the plant management's response. Inspection personnel must be aware that the establishment can propose initial actions and follow up in writing. The NR contains separate sections for immediate and further planned actions. Verbal assurances from the establishment are acceptable as long as they are consistent with the establishment's documented follow up response. If a pattern of inconsistent responses

develops and continues, inspection personnel should request written responses or assurances for corrective measures before determining resolution on official control actions. Inspection personnel must document plant responses on the NR if plant management refuses to document them. Supervisors must determine whether inspection personnel are accepting appropriate **corrective actions** from plant employees when noncompliance occurs. Inspection personnel should be ensuring that plant corrective actions address **all three** of the requirements (1) procedures for disposition of affected product; (2) restoration of sanitary conditions; and (3) prevention of recurrence of direct product contamination or adulteration. If **any** of these conditions are not met, inspection personnel should **maintain the official control action** in place until acceptable corrective actions have been provided by the establishment.

Inspection personnel should be able to determine from the plant's response pertaining to an SSOP noncompliance whether the noncompliance is due to a problem with the **design** of the SSOP or the **execution** of the SSOP. When the problem is due to the design of the SSOP, the SSOP will need to be modified by the establishment. When the problem is due to inadequate or inappropriate execution of the SSOP, the establishment will need to improve its implementation of the SSOP. This considered, supervisors should determine that **inspection personnel are not identifying or requiring that plant personnel take any specific corrective actions**. This type of direction to plant employees from inspection personnel would be a return to the command and control style that is being eliminated by the PR/HACCP regulation. **Maintenance of the SSOP is the establishment's responsibility** and revision of the SSOP must be initiated and accomplished by the responsible plant personnel. Inspection personnel are not to direct plant

modifications or revisions to the SSOP. However, when noncompliance is due to the design or execution of the SSOP, inspection personnel are authorized to maintain official control actions until the establishment has addressed the corrective action requirements in 416.15.

(5) Supervisors must determine if inspection personnel are using the appropriate process to determine if a **systems failure** exists related to SSOP noncompliance. The first question that should be answered is, “Was adulterated product produced?” If yes, the second question is, “Is there noncompliance with the same root cause?” In other words, is the repetitive noncompliance the same and/or related repetitive noncompliance occurring due to the negligence, ineffective method, or incomplete execution by the plant? Professional analysis must be used when making this determination. Inspection personnel must review previous NRs and PDRs. The documentation must make a linkage to the previous noncompliance. **It is the combination of failed monitoring, plant response, and failed implementation of immediate and further planned actions that leads inspection personnel to consider a system inadequate.**

d. Enforcement actions - If the inspector determines that there is a **systems failure**, he or she should follow the enforcement actions outlined in Part Three of FSIS Directive 5000.1, III.C.1. This action is identical to that which is taken when the establishment fails to meet the basic requirements.

- ▶ **Advise the establishment management orally** of the findings on which the withholding action is based, and as soon as possible, **provide the establishment management with a copy of the NR** that documents noncompliance finding(s).
- ▶ **Withhold inspection**, which includes refusing to permit the labeling, stamping, or tagging

of any livestock product or poultry product produced under the noncomplying conditions as “inspected and passed” or “inspected for wholesomeness.”

- ▶ Identify all possibly adulterated livestock and/or poultry products as “**U.S. Retained.**”
- ▶ Identify violative equipment, utensils, rooms, or compartments as “**U.S. Rejected.**”
- ▶ **Notify the District Office** of the action(s) taken.
- ▶ The District Office will assign a **Compliance Officer** to work with inspection personnel to develop a **case file**. The District Office will give inspection personnel **further instructions**. For example, the District Manager may place the withholding action **in abeyance**. In this case, the plant is required to provide **written assurances** that it will bring itself into compliance. This does not mean that the enforcement action has ended. If the plant fails to follow its written assurances and bring itself into compliance, the withholding action will be reinitiated.

If the inspector determines that there is an **SSOP failure to prevent direct product contamination or adulterated product** but is NOT able to determine that there is a systems failure, then the enforcement action should follow Part Three of FSIS Directive 5000.1, III.C.2.

- ▶ Take **official control action** as appropriate. Maintain the official control action until the establishment has taken the corrective actions required in part 416.15.
- ▶ Advise establishment management by providing a **copy of the NR** that documents the noncompliance finding(s).
- ▶ **Complete documentation of establishment action(s)** to bring itself into compliance.
- ▶ Notify the **District Office** if the establishment does not bring itself into compliance.

If the SSOPs failed to prevent direct product contamination or adulteration, then there is either a design failure or execution failure of the SSOPs. With SSOP failures, inspection personnel should always be alert to the same and/or related noncompliance that have resulted in direct product contamination or adulteration. Inspection personnel must be aware that the documentation of a recurring pattern of noncompliance leads to the determination of a systems failure.

Just as for HACCP basic requirements, Circuit Supervisors should exercise their role as program advocate and communicator to assure the **IIC** that he or she is **empowered** to contact the District Office directly when they take a withholding action. Again, because the FSIS tradition is to follow the chain of command, IICs may need some **encouragement** to do this. As communicator, supervisors should explain to inspection personnel that the purpose of having a Compliance Officer get involved, when warranted, is to work with inspection personnel as a team member to document a case. Supervisors should be proactive by working on the system in covering these points with inspection personnel and **correlating with them on methodology and procedures during IPPS visits** so that when a withholding action is taken, supervisors are confident that inspection personnel understand the requirements and how to apply them correctly. For example, when making plant visits, Circuit Supervisors can review completed NRs, and discuss with inspection personnel the observations that were made, the documentation that exists, and information about any withholding action that occurred. Some of the following questions could be asked. Do inspection personnel initiate official control actions based on plausible evidence or supportable conclusions? Do inspection personnel allow the establishment to execute its SSOP?

3. *Salmonella* sampling

a. Regulatory requirements: To show that HACCP-based process control systems are achieving acceptable food safety levels, the Agency has set *Salmonella* **performance standards** for raw meat and poultry and for ground products. Details about *Salmonella* testing are covered in the Participant's Handout of Module 4b and 9a of the HACCP training. The goal of the *Salmonella* testing program is to verify that each establishment's pathogen reduction performance meets the current *Salmonella* standards. To meet the standards, each establishment must reduce *Salmonella* contamination on its meat and poultry products to a level below the current national baseline. *Salmonella* testing requirements differ from the requirements for *E. coli* testing in that there are **performance standards** set for industry. Performance standards are regulatory requirements which are **enforceable** by FSIS. Establishments must consistently meet the *Salmonella* performance standards. For *Salmonella* testing, FSIS inspectors collect samples for **beef, swine, chicken, and turkey carcasses and ground products**, which consist of ground beef, fresh pork sausage, and ground chicken and turkey. Because *Salmonella* is more likely to be present on raw, ground, or comminuted products than on carcasses, raw, ground, and comminuted product is the focus of FSIS compliance testing in establishments that slaughter and produce raw ground product. Mechanically separated product will not be included in FSIS sampling of ground product for *Salmonella*. The compliance phase of *Salmonella* testing starts the day the plant is required to come under HACCP inspection.

b. Sampling procedures: The procedure 05A03 in the ISP deals with *Salmonella* sampling. Details about the sampling requirements are covered in the video and

accompanying Directive, “*Salmonella* Analysis: Collecting Raw Meat and Poultry Product Samples.” FSIS inspection personnel will conduct the *Salmonella* testing according to the information printed on FSIS Form 10,210-7 which lists which product to sample. The sampling must be done aseptically to avoid contaminating the product. The following table shows the type of sampling, the sites for collecting the sample, and the point in the process to collect the sample.

Collecting <i>Salmonella</i> Samples					
	<u>Beef Carcasses</u>	<u>Swine Carcasses</u>	<u>Chicken Carcasses</u>	<u>Turkey Carcasses</u>	<u>Ground Product</u>
Type of sampling	sponge	sponge	whole bird rinse	sponge	25 grams collected from various locations
Sites	flank, rump, brisket	belly, ham, jowl	N/A (whole bird rinse)	back and thigh	with- in the lot; after grinding, before sea- sonings/ spices added (when possible) and before final packaging
Point in the process to sample product	after chilling for 12 hrs.		after chiller and after falling from drip line (exception: hot-boned carcasses sampled after final wash)		

Using the appropriate sampling technique is very important to assure uniformity in sampling results. All samples must be kept refrigerated (never frozen) and under security. Samples are to be shipped by an overnight delivery service on the same day that samples are

collected. If any of the shipping supplies are missing, inspection personnel must contact the Technical Services Laboratory designated on the request form to request them.

Supervisors should exercise their role as communicators and leaders by observing inspection personnel and providing feedback as they collect *Salmonella* samples to insure that the sample is being handled and shipped properly. Some examples of points to correlate with inspection personnel on include: making sure inspection personnel are prechilling open shipping containers a day before collecting the sample; using an appropriate amount of the buffered peptone water; selecting samples randomly; sampling untrimmed carcasses; using the appropriate sampling techniques; collecting the samples aseptically; using the appropriate shipping containers for the type of product (e.g., neon orange for beef and swine, neon green for poultry, and neon pink for ground product); storing samples in a secure cooler or refrigerator; and using the appropriate mailing techniques. Questions to ask during correlation with inspection personnel include: Are Inspectors using the right sampling technique and taking samples at the right frequency? If not, why not?

c. Determining compliance/noncompliance - The verification and documentation for *Salmonella* requirements will be handled by the District Office. Supervisors need to be sure that **inspection personnel** understand their **key role** in *Salmonella* sampling for the Pathogen Reduction/HACCP regulation is **sampling**.

d. Enforcement actions - Inspection personnel will receive information on taking any regulatory action other than sampling from the District Office. The FSIS laboratories will make the determination about compliance with the regulatory requirements and

will notify the District Office. If a performance standard is exceeded, the District Office will notify appropriate inspection personnel and give instructions on the course of action. The establishment will be required to take immediate corrective action to lower the incidence of *Salmonella* on all of the product of that type it produces. The effectiveness of the corrective action will be measured by subsequent testing. The regulation requires the establishment to reassess its HACCP plan upon the 2nd failure. If the establishment fails to meet the performance standard on three consecutive series of samples, this constitutes a failure of the SSOP and HACCP systems. Attention will be focused on the HACCP system. Each failure will be handled on a case-by-case basis from the District Office. Supervisors need to communicate with **inspection personnel** to be sure that they understand that they will get **instructions from the District Office on taking enforcement action when an establishment fails to meet the *Salmonella* performance standards.**

4. Consumer Protection - “Other consumer protection” refers to the regulatory requirements for consumer protection against activities such as misbranding, mislabeling, or economic adulteration. It also includes the regulatory requirements for facilities, including lighting, structural, outside premises, and product-based facility requirements. These are covered in FSIS Directive 5400.5. In the Inspection Procedure Guide (ISP), “other consumer protection” is covered under activity 04 (Economic/Wholesomeness) and 06 (Other requirements). The ISG (which will continue to be used in establishments until they are subject to the Pathogen Reduction/HACCP regulations) is organized product by product and task by task. The ISP, which will be used in establishments subject to the Pathogen Reduction/HACCP

regulations, is arranged based on the new regulations and performance standards. The inspection procedures related to food safety that were previously intermingled with economic and/or wholesomeness issues have been separated out and included under activity 01 (SSOP), 03 (HACCP), or 05 (Sampling).

a. Regulatory requirements - HACCP has not changed the regulatory requirements related to misbranding, mislabeling, and economic adulteration. Industry is still responsible for **producing unadulterated product and labeling it truthfully**. When contamination or adulteration occurs, the establishment has the responsibility to bring itself into compliance by controlling the immediate situation, taking actions to address proper product disposition, and taking measures to prevent the recurrence of the problem. Actions that do not address all of these requirements are inadequate.

b. Inspection procedures - The way in which inspection personnel will need to perform in-plant other consumer protection procedures such as net weight checks, FPS, batter and breading pick-up tests, verification of compliance with requirements for pest and rodent control, etc., **has not changed**. FSIS will continue to have responsibility for ensuring that adulterated product does not enter commerce, even though this type of adulteration is not a food safety hazard. If product is being misbranded, mislabeled, or economically adulterated, inspection personnel will document the noncompliance on an NR and take appropriate official control actions when necessary.

c. Determining compliance/noncompliance - The Deficiency Classification Guide will no longer be used in establishments that are subject to the Pathogen Reduction/HACCP regulations. The Noncompliance Determination Guide will cover all areas of FSIS regulatory responsibility. When noncompliance occurs, the appropriate noncompliance trend indicator will be marked on the NR and the PS. A copy of the NR will be given to plant management.

There are two basic types of trend indicators: product trend indicators and facility trend indicators. For product trend indicators, there are three possible choices: economic, misbranding, and protocol. For facility trend indicators there are four possible choices: lighting, structural, outside premises, and product based. Each of these are discussed in the following pages.

Product Trend Indicators

- **Economic** - This trend indicator is used when noncompliance with an 04 procedure is determined **prior to the labeling or branding of a finished product**. Examples include wholesomeness defects found during a boneless meat procedure that exceed regulatory requirements, inaccurate scale being used to determine net weights, or product is found during production to contain more solution than allowed by regulation.
- **Misbranding** - This trend indicator is used when noncompliance is found when performing procedures 04 or 06A elements **after the product is labeled, branded, or packaged**. For example, it would be used for net weight, labeling, and product standard of identity noncompliance.
- **Protocol** - This trend indicator is used when the establishment is using an **alternative method** for producing a product or conducting a process that is not food safety related and it **differs from regulatory requirements** and noncompliance is found. The noncompliance is determined while performing a procedure in an **04 element**.

Facility Trend Indicators

- **Lighting** - This trend indicator is used when there is noncompliance with lighting requirements (e.g., inadequate intensities, unprotected non-shatter proof bulbs directly

over exposed product).

- **Structural** - This trend indicator is used when structural requirements are not met (e.g., holes are found in production area flooring, walls and ceilings; equipment not in use; inedible or condemned product is not separated from edible product areas).
- **Outside premises** - This trend indicator is used when there is noncompliance with outside premise requirements (e.g., accumulations of rubbish are found outside of the plant).
- **Product based** - This trend indicator is used when there is noncompliance involving product or product area that does not result in misbranding, mislabeling, direct product contamination, or insanitary conditions covered by the SSOPs. For example it should be used when product residue (e.g., fat, meat scraps) from the previous day's operations are found on the leg of a table or stand in the production area.

Until an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an NR, the NR is “open.” Inspection personnel are to review the file of “open” NRs daily. When an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in the issuance of an NR, inspection personnel are to file the NR as “closed.” The IIC is to meet with establishment management weekly to discuss noncompliance findings (if any) and action(s) taken by the establishment to bring itself into compliance.

Just as is done for HACCP requirements, FSIS will use trend indicators in determining whether to take additional regulatory or administrative action based on establishment performance. Documentation of recurring or repeated noncompliance with regulatory requirements will be used as a basis of further FSIS action.

Supervisors should execute their role as communicators, evaluators, and program advocates by correlating with inspection personnel to be sure they understand **how to use the trend indicators**. For example, inspection personnel who find noncompliance when performing procedures in an 06D, 06E, or 06F element should select among indicators based on the root cause of the noncompliance. Noncompliance resulting from a slaughter flooring problem should be classified as structural; noncompliance due to leaking pipes on an unenclosed loading dock should be classified as outside premises. In some cases, if inspection personnel find noncompliance with equipment that does not involve product, the facilities trend indicator can be used (e.g., the equipment is not being used in production). However, if there is direct product contamination on equipment that is “ready for use” with exposed product, an SSOP trend indicator should be used.

Just as is done with HACCP requirements, supervisors must assess whether inspection personnel documentation in **section 10 (Description of Noncompliance) of the NR** creates a clear and accurate description of the noncompliance. The noncompliance should be described in objective terms. It is essential that the information be clear and descriptive, allowing the reader to visualize the noncompliance. The NR must contain the provision(s) of the regulation(s) with which the establishment failed to comply. Previous noncompliance for the same root cause should

be included in the documentation if warranted. Also, the failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration as documented previously should be included.

d. Enforcement actions and phase out of PEA - When significant misbranding or economic adulteration are suspected, inspection personnel are to continue to take action as appropriate, such as applying a, "U.S. Retained/Rejected," tag to misbranded or economically adulterated product, to control the product. Inspection personnel are to notify the **District Office** if the establishment does not bring itself into compliance. Inspection personnel should always be alert to the same and/or related noncompliance that have resulted in direct product contamination or adulteration. Inspection personnel must be aware that the documentation of a recurring pattern of noncompliance leads to the determination of **ineffective process controls**. When a situation of repetitive noncompliance is identified, inspection personnel are to notify the District Office. The District Office will have flexibility in developing strategies to deal with economic and misbranding noncompliance. PEA is being phased out. However, District Managers are expected to take strategies that were useful from PEA such as enhanced enforcement actions which were part of Stage 1, Step 2 of PEA, and apply them to current situations.

Supervisors should ensure that inspection personnel are continuing to take appropriate regulatory actions for noncompliance related to significant misbranding, mislabeling, and/or economic adulteration. Supervisors should advise inspection personnel that if the noncompliance with requirements only involves a failure that the responsible establishment official **can correct**

effectively and immediately (e.g., the inspector observes a mouse running under unused equipment and supplies stored on the ground outside of the plant), inspection personnel will provide establishment management an opportunity to bring the establishment into compliance. No official control action is necessary, but the failure will be **documented on the NR** and the PS by inspection personnel with a statement that the situation was immediately corrected. However, if noncompliance involves a failure that cannot be corrected effectively and immediately, the IIC should take the appropriate official control action. Supervisors need to communicate with inspection personnel so that they understand that a **variety of strategies** can be used to deal with economic misbranding noncompliance.

5. **Zero tolerance for fecal contamination** - Because fecal material is a vehicle for microbial pathogens, critical control point(s) to prevent and eliminate contamination with visible fecal material are predictable and essential components of all slaughter establishments' HACCP plans. **The Agency has not dictated where the CCPs should be or how the limits should be met.** Therefore, the CCPs may be before or after the point that FSIS verifies. However, the **point of FSIS verification is at the final rail in red meat prior to the chiller in poultry.** The following points cover the verification, documentation, and enforcement procedures when the inspector finds fecal contamination on product after the final rail in red meat or just prior to entering the chiller in poultry slaughter establishments.

- **HACCP verification procedures by FSIS inspection personnel are the same in slaughter as in other processes.** That is, there is a HACCP 01 and a HACCP 02 procedure, each with (a) recordkeeping and (b) review and observation components. The

IIC or off-line inspector performs “HACCP verification” for fecal contamination as a part of the overall verification of the HACCP system in slaughter operations.

- If fecal contamination is found **after the final rail in red meat slaughter** establishments or on **poultry carcasses at the entrance of the chiller or beyond** through the performance of FSIS HACCP verification procedures, then this is considered a **deviation from a critical limit** (regardless of the location of the CCP). This is considered monitoring noncompliance, and FSIS will verify corrective actions as per 417.3(a). This is **not a system failure** at this point.
- If this is part of an **03J01 procedure** (Slaughter; review of random sample of HACCP plan features in operation), then an **NR** would be issued and the 03J02 procedure would be performed to verify the corrective actions, etc.
- If this is part of an **03J02 procedure** (Slaughter; procedure for reviewing implementation of a HACCP plan for a particular product), the establishment is **verbally notified** of the monitoring noncompliance and the 03J02 procedure is completed, including verification of the corrective actions. An **NR** is issued upon completion of the 03J02 procedure.
- A determination of an **inadequate system** will be made based on **repetitive noncompliance** with the zero tolerance standard for fecal contamination, and the NRs documenting an **ongoing occurrence** of failed implementation and/or execution of effective immediate and further planned actions. *(FSIS will issue directives for both red meat and poultry.)*

D. The role of the supervisor in providing technical advice

Traditionally, supervisors served as the primary source of technical information for in-plant inspection personnel. However, because FSIS has adopted a more scientific approach toward meat and poultry inspection, the need for technical information grows daily. The Pathogen Reduction/HACCP regulations allow industry more flexibility their approaches to meet the regulatory requirements. This is likely to increase the type and magnitude of industry innovation. There will be at least as many HACCP plans as there are plants in operation. Because of this variety, decisions are sometimes not as clear cut as they were with command and control regulations. This environment of changing regulations and industry innovations make it very difficult if not impossible for supervisors to be aware of all of the technical requirements. Supervisors are no longer expected to be the primary source of technical information for in-plant inspection personnel. The Technical Service Center has been established to provide technical advice and assistance. As was outlined in Module 10 of the HACCP training, the Circuit Supervisor will regularly handle questions concerning policies, procedures, and associated standards. However, when they are not available, inspection personnel can send questions directly to the Technical Service Center. The preferred method of contacting the Technical Service Center is through HP Desk or e-mail with a copy of the question to the supervisor. This is covered in detail in Module 10 of the HACCP training.

Because the change in regulations affects inspection procedures, the primary role of the supervisor will be to see that the appropriate methodology that is described in the HACCP training modules and in this guide are used and that enforcement is carried out appropriately by

inspection personnel. One way to view the current situation is that both inspection personnel and supervisors are on a fairly “level playing field” with regard to their knowledge and understanding of the technical requirements. Both inspection personnel and supervisors will need to contact the Technical Service Center with questions.

E. Using the PBIS data

The automated system of the Performance Based Inspection System (PBIS) will continue to create reports based on data entered into the ADP system. These data include documentation on procedures performed by inspection personnel and information from inspection personnel regarding establishment noncompliance (from the PSs and the NRs). There will be 12 basic MIS reports that can be generated. Supervisors are expected to continue to use the reports in evaluating establishment noncompliance (including trends) and to support management decision making. A review of the new MIS report and suggestions for using the PBIS data follow.

1. Review of new MIS report - One of the culture changes that is being made as a result of implementing the new regulations is a stronger emphasis on the use of quantitative data and information for decision making. Supervisors are expected to use the MIS report as a decision making tool. The new MIS reports will be structured like the old MIS reports, although the type of information presented will change. The reports should be more flexible, in that they can be tailored to target the information that the supervisor needs. The reports will be District and establishment based, and can be generated more rapidly than in the past (e.g., daily or weekly, not just monthly). The Establishment Summary Condition Report which was done by CCP will now be done by element. Supervisors can request reports for any date desired. There will be a volume

of paper to examine. Reports by element will show the number of procedures performed, the number not performed, and total noncompliance. Because the system is new, there is no clear expectation about what the national data will look like. After an implementation period, supervisors will be asked to provide feedback concerning how the MIS reports are being used, the trends that are being identified, etc.

2. Suggestions for identifying trends - Although there are no firm expectations about the trends that will be found in the national data, there is an expectation that the data will provide information that is useful for management of the inspection system. This section contains some suggestions on how to use the MIS reports. These suggestions are not meant to describe the full range of possible uses for the data that is generated by the PBIS system. Supervisors are encouraged to be innovative in using the reports to manage the inspection system.

Supervisors can rapidly scan activities, elements, and procedures to identify trends. For example, MIS reports can be generated for procedure 03A01 to see the number of basic HACCP procedures that were performed. At least one basic HACCP procedure should be performed in all large plants shortly after the implementation date.

The new system will allow supervisors to combine any grouping of establishments to make up a report. The reason for combining establishments in a report is to compare them.

Supervisors can also look for trends across requirements. For example, if there is noncompliance for SSOP requirements, are there any similarities regarding the noncompliance for HACCP requirements or the microbiological sampling requirements - such as failure to take the appropriate corrective actions? Supervisors can also examine the percentage of noncompliance

by element for a period of time for an establishment. Is it going up or down? Is it high at one period of the year and low at another period?

The Weekly Summary Condition Reports are helpful when the establishment is starting a new procedure. The supervisor can review the reports over time to see how things changed. For example, are there particular periods of time during the year that noncompliance is likely to occur?

For the Procedures Summary Condition Report, the “no feedback” column will identify a procedure that is not being performed. This could be cause for the supervisor to investigate why the procedure is not being performed. One reason might be that the establishment has changed its operations, and the Plant Profile needs to be updated. Another reason might be that inspection personnel need assistance to perform the procedure.

Supervisors are encouraged to make use of the new reports and keep track of the reports and combinations of data that are most effective in managing the inspection system.

Index

<u>Page(s)</u>	<u>Topic</u>
12	Basic procedure - purpose
42-43	Corrective action procedures (HACCP other features)
64	Corrective action procedures (SSOP other features)
26-31	<i>E. coli</i> basic regulatory requirements
31	<i>E. coli</i> checklist
31-34	Enforcement actions related to <i>E. coli</i> basic procedures
19-21	Enforcement actions for noncompliance with HACCP basic requirements
55-58	Enforcement actions for noncompliance with HACCP other features
82-83	Enforcement actions for noncompliance with other consumer protection requirements
76-77	Enforcement actions for noncompliance with <i>Salmonella</i> sampling requirements
23-26	Enforcement actions for noncompliance with SSOP basic requirements
70-73	Enforcement actions for noncompliance with SSOP other features
8-12	Establishment/shift procedure plan and work assignment
17-19	FSIS Form 5000-1 (HACCP basic checklist)
22-23	FSIS Form 5000-2 (SSOP basic checklist)
31	FSIS Form 5000-3 (<i>E. coli</i> checklist)
17-19	HACCP basic checklist
13-16	HACCP basic regulatory requirements
35-38	HACCP other features

<u>Page(s)</u>	<u>Topic</u>
14-15	Hazard analysis
2-3	Implementation dates
65	Implementation procedures (SSOP other requirements)
51-53	Inadequate HACCP system - making the determination
86-88	MIS reports
40	Monitoring procedures (HACCP other features)
64	Monitoring procedures (SSOP other features)
54-55	NR Continuation Sheet for HACCP procedures
68	NR Continuation Sheet for SSOP procedures
78	Other consumer protection requirements
86-88	PBIS data
43-44	Plan reassessment procedures (HACCP other features)
5-8	Plant awareness meeting
6	Pre-shipment review by establishment during plant awareness meeting
47-48	Pre-shipment review - advice to supervisors
22-23	Procedure 01A01 (SSOP basic procedure)
17-19	Procedure 03A01 (HACCP basic procedure)
41-42	Record keeping procedures (HACCP other features)
65	Record keeping procedures (SSOP other features)
73	<i>Salmonella</i> sampling requirements
26-31	Sampling requirements for generic <i>E. coli</i>

<u>Page(s)</u>	<u>Topic</u>
21-22	SSOP basic regulatory requirements
22-23	SSOP basic checklist
58	SSOP - changes in terminology
58-60	SSOP other requirements
70	Systems failure (SSOP)
48-50	Trend indicators for HACCP other features
79-80	Trend indicators for other consumer protection requirements
64-65	Trend indicators for SSOP other features
8	Updating plant profiles
40-41	Verification procedures (HACCP other requirements)
10-12	Work assignment
48	Zero tolerance - advice to supervisors
83-84	Zero tolerance for fecal contamination (its relationship to HACCP plans)